UNITED STATES OF AMERICA { PRIVATE }

+ + + + +

ARMED FORCES EPIDEMIOLOGICAL BOARD

+ + + + +

MEETING

+ + + + +

WEDNESDAY

FEBRUARY 20, 2002

+ + + + +

SAN DIEGO, CALIFORNIA

+ + + + +

The Board met at the Island Club, North Island Naval Air Station, San Diego, California, at 7:20 a.m., Dr. Stephen Ostroff, presiding.

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(7:20 a.m.)

DR. OSTROFF: Good morning. It's good to see such a large crowd for the second day. We have an extremely ambitious schedule for today as well. Usually, the second day is a little bit quieter than the first day, but that's not the case at this particular meeting.

I just want to say I think -- on my own personal behalf but as well as for the board -- I give our thanks to Captain Schor who's not here and to the Marines for the absolutely fantastic tour that they gave us yesterday. It's extremely impressive.

I personally would like to take a couple of those drill instructors home with me to get my troops into shape because they're really an amazing group of people.

The other thing, I think, that, you know, is quite striking to me is -- and I think all of the board members probably were impressed -- is I have never seen so many people on crutches, and there's no question that we -- if you can take a message back to Captain Schor, that we want to hear more about -- as these programs go forward -- to look into some of the epidemiology of these orthopedic injuries because it's absolutely astonishing to me to see that many young people on crutches.

With that, I'm going to turn it over to Rick.

LT. COL. RIDDLE: Yeah, what we want to do this

morning is -- actually, Leslie is with us this morning -- if we could ask her to come up and also Dr. Ostroff -- I wanted to go ahead and present Leslie with this certificate from Dr. Winkenwerder. Jennifer Strickler is not here today, but she also held -- but Leslie kind of spearheaded the efforts out for helping us set this meeting up, and all of the NHRC staff, so on behalf of Dr. Winkenwerder --

DR. OSTROFF: Thank you so much.

LT. COL. RIDDLE: So if we could give the NHRC staff a round of applause.

(Applause.)

LT. COL. RIDDLE: So also today, if you could, is -- for questions from the audience, please go to one of the microphones on either side of the table here, and then for the board members, if you could identify yourself and also the speakers for a question -- it will help out with the transcription services.

Again, today, you know, the meeting is being recorded. There may be people from the public or the press in the audience. Lunch today is available here at the club. They have a turkey, prime rib lunch buffet for $7.95 which is a pretty good deal.

You can also have lunch over at the golf course, the 19-hole golf course -- or several other places on base.

If you have any travel arrangements today, please

see Lisa or Karen out here so that we can make those arrangements and take care of the travel arrangements and even tomorrow so we make sure we can get you out -- arrange for a taxi and trip to the airport.

So with that --

DR. OSTROFF: Very good. I think we're going to move on to the presentation that we didn't have yesterday from Commander Russell, and I was very interested, as we were over at the Marine Corps Recruit Depot, that they mentioned on several occasions that they had had several epidemics of pneumonia within the last year or so, and so now everyone is getting a pneumococcal vaccine, and I'll be very interested to hear.

CMDR. RUSSELL: Thank you very much. Good morning, ladies and gentlemen. It's a pleasure to be here this morning, and I'm glad to see that San Diego has provided a little bit better weather, and I understand it's going to be a nice day. So welcome to San Diego.

It's an honor to have the opportunity to talk to you this morning about a very large, double-blind, placebo-controlled trial of the 23-valent pneumococcal vaccine among military trainees at increased risk for respiratory disease.

I'm going to talk a little bit this morning about the background briefly -- I think this panel knows a lot about the background -- the rationale behind the need for this study, the design of the study itself, some of the results to date, and

I'm going to spend a little bit of time about the two unblindings that we have done so far to date.

One of the very large strengths of this study is our many collaborators. Some of those are co-investigators and are in the audience -- Dr. Greg Poland from the Mayo Clinic is with us. The father of this study, Dr. Greg Gray from the University of Iowa, is also with us.

The four recruit training sites that are absolutely instrumental in this study are the -- is the Marine Corps Recruit Depot, Parris Island; Fort Jackson; Fort Leonardwood; and Great Lakes Recruit Training Center.

Oh, also I should mention that the collaboration that was forged by Dr. Gray with Wyeth-Lederle Vaccines has been very important to this study also. They do provide the vaccine and placebo to us free of charge and in a blinded fashion.

So, briefly, pneumococcus -- it's very clear to this audience that pneumococcus is responsible for a lot of morbidity and mortality in the world. There are over 90 serotypes; 23 of these obviously are in the vaccine that we are testing. It is estimated that that vaccine covers about 90 percent of the illness that is seen in the United States.

A recent publication in '94, I believe, by Dr. Gray looked at hospitalizations for pneumonia, found about 12 percent of them were as a result of strep pneumonia.

There have been various outbreaks which have been

mentioned also this morning that have affected military troops. Camp Pendleton has been one that has been hit rather hard in '89 as well as in November of 2000.

Together with outbreaks, the fact that the strep-pneumo bacteria itself is changing considerably in respect to antibiotic resistance is important.

Historically, this pathogen has been very sensitive to penicillin, but in recent years there's been more and more studies that have shown intermediate to high resistance to penicillins, and many of those have also been resistant to other antimicrobials.

We received samples at NHRC from many military treatment facilities. These are strep-pneumo isolates that are collected and cultured at different military treatment centers. They are sent to us, and we do antibiotic resistance on those as well as serotyping, and of those we found that 35 percent have intermediate or high-level resistance to penicillin, and 24 percent are actually multidrug resistant.

So, again, this is a big problem. The fact that there are outbreaks has led to the need to look very seriously at primary prevention.

History of the pneumococcal vaccine itself -- shortly after World War II, there were two six-valent preparations that were on the market. In '77, a 14-valent preparation -- but in '83, two companies, Wyeth and Merck,

produced a 23-valent vaccine.

As I mentioned, it is estimated to cover 85 to 90 percent of the serotypes that cause invasive infections in the U.S.

It is recommended for various high-risk groups, for groups over age 65, individuals with chronic pulmonary disease, chronic cardiovascular disease.

In 1997, the ACIP broadened that to age groups 2 to 64 that lived in environments of high risk, and in 1998 this board called for a controlled study of this pneumococcal vaccine in our recruits.

There was the desire to base policy on some good, rigorous science rather than extrapolation from other populations and other studies.

I think it's of interest to note that the vaccine is being used in various populations in the military now. BUDS and Rangers trainees receive this vaccine year-round. MCRD here in San Diego used it seasonally until 2000 which you saw in an earlier slide -- that large outbreak in 2000 at which time they started using it continuously, year-round.

However, again, the actual effectiveness in these populations has not been well-defined.

This study was designed based on the recommendations of this board, and the primary objective is to compare the benefit of employing this vaccine in our recruits.

The primary outcome we're looking at is all-cause pneumonia and acute respiratory disease between trainees who receive the vaccine and those who receive the placebo.

The total sample size for this study over a two-to-three-year period is 191,000. This sample size was based on an estimate that in an unvaccinated population there would be approximately 11 pneumonias per 1,000 person-years.

The vaccine is 70 percent efficacious, and 20 percent of pneumonias that we would see would be caused by strep pneumonia, and also an attrition rate of approximately 12 percent.

You see here in this slide some recruits at training being consented -- they're consented en masse. They read the informed consent, get signatures and permit the injection that is usually given in line with all of the other injections.

It's unfortunate you weren't able to see that in your tour yesterday. It's quite a sight, seeing the recruits go through the vaccination process.

After a person is enrolled in the study, they are actively followed for pneumonias during their stay at the recruit training center which is from eight to 12 weeks.

If a recruit that is entered in the study is found to have a pneumonia, then they are -- a medical workup is performed that includes blood culture, CBC, chest X-rays, sputum

cultures, three throat swabs and acute and convalescent sear -- the convalescent is taken approximately two weeks later.

At the end of this eight-to-12-week period, there is an end-of-training questionnaire that then looks at symptoms of acute respiratory disease during their training period.

However, a big strength of this study is the fact that we're following these people beyond this active surveillance period, this period that they're in the recruit training site.

For an individual that was entered into the study in October of 2000, they would be followed until the end of the study, so they may be followed for up to three years.

A person that's entered, say, today would be followed again until the end of the study, so about -- maybe an additional year, and these people are followed through various passive databases that we have mentioned in this forum including the standard inpatient, standard outpatient and the HCSR which is a database looking at medical encounters in the civilian world.

To date, we have entered as of early February -- we have enrolled over 80,000 individuals, so this is a huge effort, and our research assistants on the sites that do this enrolling have -- we really need to applaud them in their efforts. They've done a phenomenal job.

Here is a slide looking at actual pneumonias per site through -- since the initiation of the study. We saw a large peak at Great Lakes in early February. All data for early

'02 is not in yet, but we haven't seen a large spike this winter yet.

These are our laboratory results to date from those radiographically confirmed pneumonias. You'll see that nearly half of them are -- have been diagnosed as adenovirus, about 13 percent microplasma pneumonia, 14 percent chlamydia pneumonia.

Of note here is we have not received an isolate for strep pneumonia from a radiographically confirmed pneumonia. We have received a strep isolate from an individual that unfortunately died of a bacterial meningitis, and the strep pneumonia was isolated from their CSF.

This individual received a placebo vaccine. We have received that isolate, worked it up; it was not typeable by any of the vaccine serotypes in our lab. It's been forwarded on to Dr. Musher's lab. He has confirmed that it appears to be unencapsulated. He's working that up further for comparison of other unencapsulated forms that have been noted in the military population.

Now, I think it's important to note at this point that it's fortunate that this study is not dependent on strep pneumo isolations. As I mentioned, the primary outcome is all-cause pneumonia, all-cause ARD's.

However, it's obviously important. It is among the secondary objectives.

I've spent a lot of time recently trying to figure out if there's some way we could improve our diagnostic capabilities with S-pneumonia. We do have a pretty rigorous capability at the lab at NHRC. We have various PCR techniques with microplasma pneumonia and chlamydia pneumonia, a variety of ALIZA (ph) and immunofluorescent techniques that aid us in the diagnosis.

But for people that are familiar with serologies and other diagnostic capabilities for strep pneumonia, there simply is not good tests out there.

There have been recent debates in the literature by some of those that have developed the tests that are out there, again admitting to the fact that testing -- that diagnostic testing for strep pneumonia is suboptimal.

I want to move now into the unblinding process. We requested in our protocol to do this twice a year.

Our first unblinding in August 2001 went through the end of March which was about six months after the initiation of this study. This kind of delay from the end of March to August before we can actually do the blinding is a result of the delay in data actually getting into the passive databases.

At this time, there were 14,000 -- approximately 14,000 individuals in the denominator, 131 radiographically confirmed pneumonias, and at that time the crudes-odd ratio was right on one as well as those pneumonias by passive -- confidence

interval is pretty tight but including one.

We are currently in the process -- processes of doing another unblinding, and I've been pushing the team at NHRC pretty hard -- members of whom are in the audience -- to get some results on this unblinding for this meeting today. So last week there was a lot of work at bringing some of this together.

As of February 2, '02, we're looking at all pneumococcals that occurred through the end of September, so this would not include any pneumonias that were -- were or are being seen over this winter, again the delay because of the delay of getting data into the passive databases.

The denominator as of that time was just over 51,000, and we were trying to be a little more comprehensive in this unblinding.

The outcomes to be measured include all-cause radiographically confirmed pneumonias, all-cause pneumonia by your passive databases, which, as you would expect, are quite a bit more than you see actively because of a lot of these simply aren't radiographically confirmed -- is what we have found -- all-cause pneumonia and ARD by the passive databases.

Number four, we're looking at a severity continual variable -- that unblinding is not completed yet.

And number five, meningitis, pneumococcal or bacterial, unknown pathogen because of the one episode that we did have.

For one through three of these -- I'm not going to show you numbers right now; these are preliminary numbers, but the odds ratios are just right on one with some pretty tight confidence intervals.

So this is pretty interesting with an enrollment or denominator there of 51,000 to date, nearing a third of what will be our total study sample size.

Weakness that we need to point out real quickly in these very preliminary second and blinding numbers is the fact that we are not accounting for attrition yet. We have to get to numbers from NMCD to get -- that's not right -- NDMC -- we actually will do queries to them to get dates of when people leave the service or some of them didn't even finish recruit camp, and that's very important in this process.

Someone -- you might argue, even though it's a blinded random study, you might argue that individuals that get the placebo might be more likely to get ill and more likely to atrite (ph), and if that was the case, then these numbers would not demonstrate an effect of the vaccine that might be there.

The meningitis -- there were five cases seen in the passive databases, and they were nearly -- they're three and two in the vaccine and placebo groups.

So in conclusion, I wanted to pay credit to some of our different sites -- the individuals at those sites that made this study possible. Again, Fort Jackson, Fort Leonardwood,

Great Lakes and MCRD Parris Island. It's a very large effort. We're currently underway. There's some challenges that we're currently going through, but I'm confident we'll get through them.

Questions?

DR. OSTROFF: Thank you so much. This is just a fantastic study. Congratulations. Let me open it up. Dr. Berg?

DR. BERG: Bill Berg. Kevin, I have two questions -- I have three questions.

The 70 adenovirus isolates -- what strains were they?

CMDR. RUSSELL: We haven't typed those yet.

DR. BERG: Okay.

CMDR. RUSSELL: We will, though.

DR. BERG: My second question --

CMDR. RUSSELL: I'll add real quickly -- we haven't seen anything but four for quite awhile from our recruit camps.

DR. BERG: Okay. You've got about 32 isolates of microplasma in chlamydia -- in the four recruit training centers, how many of them are given azithromycin -- to recruits who are allergic to penicillin and -- how have you factored that into your consideration?

CMDR. RUSSELL: The Bicillin is given at -- round the clock at two of our training centers. One of the training

centers, Fort Jackson, doesn't give Bicillin at all, and Fort Leonardwood gives it seasonally.

I actually don't know what they give in the case of penicillin allergy. Do you know, Dr. Ryan? It's not azithromycin at these sites.

CMDR. RYAN: Only at MCRD San Diego did they give azithromycin -- is what we heard yesterday.

CMDR. RUSSELL: Right.

CMDR. RYAN: Otherwise it's erythromycin.

CMDR. RUSSELL: It's going to be erythromycin, yeah.

DR. BERG: Which also has activity --

CMDR. RYAN: Right -- still an important issue.

CMDR. RUSSELL: That's important to take into account in our success of culturing bacterial pathogens during this period of active surveillance, too -- absolutely.

DR. GRAY: This is Greg Gray. Actually, I think the Army doesn't give an alternate prophylaxis when they have a penicillin allergy. Jeff Gunzenhauser probably would be able to verify that.

COL. GUNZENHAUSER: That's correct.

CMDR. RUSSELL: Thank you.

DR. GARDNER: Pierce Gardner. This is a very interesting study with some rather surprising results so far, at least. The isolates that you received, I guess, are sputum

isolates, and I guess you are doing three throat swabs in each of these folk, and I'm going to ask you what the -- if the -- if it's an antibiotic issue, one might see a low rate of carriage -- ordinarily one would expect that 10 to 20 percent of people would have pneumococcus in their pharyngeal flora. What's the data on your swab?

CMDR. RUSSELL: The strep-pneumo isolates -- the strep-pneumo is the only isolate that we require the local hospital to culture and send to us. Everything else from the throat -- and they do that from blood culture and sputum. Everything else from the throat swabs and acute sera -- we get at our lab and we test by PCR.

DR. GARDNER: Are you finding --

CMDR. RUSSELL: We are not finding any.

DR. GARDNER: You are not finding pneumococcus even in the throat swab?

CMDR. RUSSELL: We are not finding positive PCR --

DR. GARDNER: Even in the throat swab.

CMDR. RUSSELL: Pardon?

DR. GARDNER: Even the throat swabs are negative.

CMDR. RUSSELL: That's correct.

DR. GARDNER: Which certainly would -- and that's just -- that's bizarre except for the idea that this is related to, I think, antibiotic use. That's got to rank high 'cause I

don't think you could go around and culture a bunch of people in this age group unless you've got an enormously different -- and not -- fine.

The other question -- I was unclear -- in the meningitis cases -- did you imply that these were not pneumococcal -- or you said something about an unencapsulated pneumococcus?

CMDR. RUSSELL: Yes, sir.

DR. GARDNER: Which would be again a -- fly in the face of what we think about the pathogenicity of this --

CMDR. RUSSELL: Of the unencapsulated?

DR. GARDNER: Yeah.

CMDR. RUSSELL: Correct.

DR. GARDNER: We haven't had -- I'm unfamiliar with the previously reported invasive meningitis with unencapsulated pneumococcus. Is there literature on this?

CMDR. RUSSELL: You're absolutely correct, and I've been discussing this with Dr. Musher who is incredibly interested in this whole process. There has actually been -- well, Lisa Pearse is in the audience, and there has been another death, although the cause of that is not for sure, but we did get a strep-pneumo isolate from that person also, and it was unencapsulated.

DR. GARDNER: So the five meningitis cases are pneumococcus or --

CMDR. RUSSELL: No, they are not. The five meningitis cases are from passive databases, and they're looking at bacterial cause, looking at again ICD-9 codes that are strep-pneumo, bacterial, unknown causes --

DR. GARDNER: And of the five, you've got two that seem to be unencapsulated pneumococcus?

CMDR. RUSSELL: One.

DR. GARDNER: One.

CMDR. RUSSELL: Yes, sir.

DR. GARDNER: Okay.

CMDR. RUSSELL: That was the one that was associated with the death.

DR. GARDNER: I guess my final question, if I might -- a lot of the questions that revolve around the use of pneumococcal vaccine have to do with the duration of protection and even antibodies, and I guess my question -- do you have built into this the opportunity to do serologies on these people or subset to see what the persistence is -- and we'd love to get some data, of course, on boosting in this age group.

CMDR. RUSSELL: Very good question, and it was actually a question that was brought up at our AIBS meeting last year -- it would be logistically extremely challenging to try and find these people after the case, but I think, when you're looking at a sample size as large as we are, it certainly could be a substudy. It is not built into this study, but again

enrolling nearly 200,000, trying to locate some of them for doing some serologies some years past in this age group would be interesting and feasible in a subset, I would think.

DR. PATRICK: Kevin Patrick -- looking at the pneumonia case load per month on the pneumonia cases by February 3rd, 2002, there's a pretty substantial difference between the locations, and I'm wondering, are you going to be able to draw conclusions about location-specific issues on this and potentially to drive policy?

CMDR. RUSSELL: We certainly plan on looking at them by location as well as combined. Great Lakes, absolutely, is always known to have a higher burden of respiratory disease, historically. If that data can be provided -- I guess policy depends on --

DR. PATRICK: I just wondered if your samples are structured in a way that you can come to some conclusions by setting.

CMDR. RUSSELL: It wasn't designed with that plan.

DR. OSTROFF: Other comments?

DR. NESS: One other comment. So it sounds like you have kind of an interesting --

DR. OSTROFF: Can you identify yourself?

DR. NESS: Oh -- Roberta Ness. It sounds like you have an interesting challenge here in that, if in fact the microbiology data are being affected by prior antibiotic use from

the data on pneumonia per se, using a radiologic standard -- may also be problematic with regard to the fact that there are obviously all these other types of bugs that are causing pneumonia, and so you may have essentially a washout effect -- so, you know, you're looking for a needle in a haystack in that case.

CMDR. RUSSELL: You're absolutely right. Two comments to that, however, is the fact that the act surveillance -- and that is a primary outcome, the actively surveilled radiographically confirmed pneumonias is only a small part of the study. The strength of looking in the passive databases for many, many months -- is where the strength is, I believe.

And -- anyway, I think that that is something we need to keep in mind when we look at that.

DR. OSTROFF: Greg, any last thoughts?

DR. GRAY: This is Greg Gray. I think this is a very important study, even if it's a negative study, because empirically what we find in the Department of Defense is that there's an episode of some outbreak, and epidemiologists are called to make a best-judgment intervention, and often without control, and it becomes -- as is the case with a pediatric vaccine over here at the SEAL training site -- something that they're afraid to take away -- that's the HIB vaccine.

So in this case, thanks very much to the board for

arming the DOD with your recommendation to do a placebo-controlled trial because I think, in the long run, if we find this intervention is effective or not, it's going to save us a lot of dollars -- either way, it's very much a strong bid -- it's tremendous that you folks supported us some years ago with this. That's speaking, of course, as if I'm still on.

(Laughter.)

DR. GRAY: Anyway, I suspect that -- we know from other studies that there are pneumococci colonizing in the throats of these trainees. It's just not been the focus of this study -- to work on that.

CMDR. RUSSELL: Just in conclusion real quickly, Dr. Ness also -- it was important in this study that we didn't go into the recruit camps and change what they're doing normally, so we didn't want to ask them not to do their Bicillin if Bicillin's something they're going to do for group-A strep regardless -- something they need to do, probably.

So evaluating this vaccine in that setting is what I think is the appropriate thing to do and looking at whether or not we're affecting morbidity in that setting is what's appropriate.

DR. NESS: Roberta Ness again. I don't want you to misunderstand my question. I think that this is an outstanding study, and I think the design is absolutely correct.

The only comment that I was really -- I think the

interpretation of my comment should have actually been that, in fact, it's terribly important to get to the final sample size because, in fact, the odds ratio may be a relatively small -- the difference may be actually relatively small between the two groups, given the fact that what you're looking at is, in fact, a range of pathogens.

CMDR. RUSSELL: Thank you very much, actually, for that comment because we are going through challenges right now with Wyeth, and although they have been incredibly supportive to now -- to this time, the actual time frame of the study has changed over the last two years than was originally forecast, so right now we're going through challenges of potentially trying to use a five-dose vaccine vial rather than the single dose that they've been providing us and finding a way to keep that blinded, double blinded, and meeting all FDA requirements as we continue the study through the 2002 summer surge without interruption. So that's among our current challenges.

And reinforcing with those people that support this study as well as Wyeth, getting to that final sample size is critical -- I think we need to keep in mind because right now what we have to say does not support the vaccine usage in this population very well.

DR. OSTROFF: Well, since Dr. Winkenwerder indicated he was going to have a conversation with them, maybe we can put this one on his plate as well. Thanks for an excellent

presentation.

CMDR. RUSSELL: Thank you.

DR. OSTROFF: We're going to move on now to the discussions of one of the questions that's before the board concerning the Recruit Assessment Program.

Our first presentation is from Colonel Gibson who's the program director for public health and a senior consultant for epidemiology in the Office of the Assistant Secretary of Defense for Health Care.

LT. COL. GIBSON: Thank you. On behalf of Dr. Winkenwerder and the Office of the Secretary of Defense for Health Affairs, I'm pleased to present these questions to the board on recruit assessment.

As a public health officer who started out at Lackland Air Force Base working with recruits, this is an area that's very near and dear to my heart and an area that I'm really truly interested in.

The issue of recruit assessment is not new. As you can see from the dates up here on the board including the DOD directive from 1997, the concept of doing assessments -- baseline assessments in recruits has been around for quite some time.

In fact, the question came to the board -- to this board in 1997 with the recommendations to go forward -- pilot-test and develop a Recruit Assessment Program.

So, in essence, what we're doing today by -- we're

bringing these questions to the board -- is presenting the results of all of that work, presenting what we -- how we have come forward with the development of a Recruit Assessment Program and asking recommendations.

The first question to the board -- and, by the way, Dr. Winkenwerder's memo or letter to the board is in your packets with further details, but the first question to the board is: Is the Recruit Assessment Program an effective instrument for the collection of baseline health data?

To help provide you with information to help answer that question, a program history will be presented by Dr. Craig Hyams who's been involved in this process for quite some time.

And then Dr. William Page will provide information on baseline health data.

The second question to the board is: Is the Recruit Assessment Program -- we're talking about the current product -- implementation feasible at all DOD recruit training centers?

The pilot work that -- we'll start out there with the pilot work by Commander Ryan and then all of the services will have an input on this issue of feasibility, which is important to the entire process, obviously.

And, finally, Commander Wah will finish up with a discussion of a CHCS-2 overview and how to integrate anything

that we come forward to into CHCS-2 and -- as we try to make this an entire process.

The goal is to come out with recommendations that we can go forward with for policy across the Department of Defense that will move us forward in this issue.

With that, I believe we're ready for Dr. Hyams. Are there any questions?

DR. OSTROFF: An old friend from the board, Dr. Hyams -- now from the VA.

DR. HYAMS: It's a real honor for me to be here today as a civilian presenting for AFEB. As many of you know, I was in the U.S. Navy until last year when I retired, and now I'm with the Department of Veterans Affairs, and I'm going to give one of the introductory presentations on the Recruit Assessment Program.

Let me just say something by introduction. This has been a long process, actually. It began at least four years ago now when a group of us from DOD, VA and HHS got together and started thinking about what were the lessons that we had learned from working on Gulf War health issues? How in the future could we provide better health care, better preventive medicine for our deployed military personnel, and also how could we answer some of the questions that were being asked about the health of our military personnel?

One of the obvious shortfalls that we had after

the Gulf War was a lack of baseline health data, data from before deployment. Without that data, it's very difficult to answer some of the questions that were being asked about the health of our military personnel. It was also difficult to tailor some of our health care interventions and some of our preventive medicine efforts, and so we came up with the idea of developing a program for the routine collection of computerized baseline health data from all enlisted and officer accessions including active duty, reserve and national guard -- to include demographic information, medical and psychological history from before entering the military, occupational history from before entering the military, and health risk factors.

And the purpose of the Recruit Assessment Program, as we called it, was to provide DOD and VA physicians with accessible medical and health risk data to aid in clinical diagnosis and care so they would have ready access to information that would let them know what the changes were in a patient's health status and also to speed the process of taking a medical history because, once some of these data is collected, you don't have to ask it again.

Another purpose of the Recruit Assessment Program was to develop and improve preventive medicine strategies in both DOD and VA, and the example we always use is the targeted mammography for individuals -- for military personnel and veterans who have a history of breast cancer in their family.

Another purpose -- and just one of the three, not the primary purpose -- was to establish baseline database to be used in future longitudinal research studies to evaluate health problems amongst military personnel and veterans and post-deployment health questions.

And, again, one of the lessons of the Gulf War was -- is that, without baseline data, after hazardous deployment, it was very difficult to understand the problems of your veterans. If you don't know whether or not the veterans after a wartime deployment had somatic symptoms before deployment, it's very difficult to sort those sort of issues out after deployment. That's just one of the problems that we had.

But there are a lot of different sort of health issues that arise after a wartime deployment that just can't be answered unless you know the status of the military personnel before that deployment.

The methods for the RAP -- we spent a long time -- this was over a year in generation, trying to determine exactly how this baseline data should be collected, what the best approach was, and what we came up with, at least for the development stage of the RAP program, was an electronically scamble (ph) paper-and-pencil questionnaire to be administered within the first three days of recruit training.

We came up with the idea of a paper-and-pencil questionnaire initially because there was already a program in

existence -- the SHIP program at Great Lakes, where they used this sort of technology to collect baseline health data -- not the sort of data that we thought should -- a lot of the data they were collecting we thought was useful, but it didn't collect as much data as we thought was needed.

Nevertheless, they had pioneered this sort of technology, and since it was already being used in one recruit center and we knew it worked, that's the reason we decided on this sort of approach to collecting this data.

Another big decision was -- is when to collect the baseline health data, and we look at three periods of time. We looked at the period of time when individuals are being evaluated at the MEPS Center. We looked at the period of time in their first week of recruit training, and then we looked down the line towards the end of recruit training and the first duty station.

And we decided, really, that the best time to collect this data was within the first week of recruit training for a couple reasons.

If you collect the data at the MEPS center, there's some empiric data from the AFMET program that you don't get as accurate responses to your sensitive questions on a questionnaire at that period of time. The recruits are just too anxious to get into the military during that period of time.

If you wait until after the recruit period, you're actually missing part of the military experience.

The idea was -- was to capture the entire military experience, the health status of the military person, from the time they entered the military, throughout their military service, and then when they entered the VA system, and that military experience begins at recruit training.

And so we decided, after quite a bit of thought, that that was the time to actually get the data. We'd get the most accurate information and the most useful information during this first week of recruit training.

It was also obvious to us that the RAP database had to be an integral part of CHCS and now CHCS-2 and that it had to have the same sort of confidentiality requirements as any routine health database in DOD and VA, and I want to emphasize this is a routine program; this is not a research program. It's a routine health database that's the start of a lifelong medical record for all military personnel and veterans.

Okay, the next hurdle we faced was developing the questionnaire, and this is still an ongoing process. We're doing testing now in the various recruit centers to really maximize the sort of questions that we want to ask and the information that we get.

And so this is a continued process, and when we started this, what we wanted was -- was a survey instrument that could be administered -- at first, we thought it would take at least two hours; now we've been able to get this down to one hour

or less. It had to be a process that didn't take an inordinate amount of time for recruit training.

As many of you know, there's really not that much time during that recruitment period for any new program. They're very rushed as it is.

So I had to do something that could be done relatively fast, and so now we've got it down to one hour less to complete the entire process.

The questionnaire had to be compatible with the already existing standard induction medical forms and with the periodic HEAR by marrying up baseline data with periodic health assessments like the HEAR. This would allow us to have a longitudinal database, a lifelong database.

Also, the questions had to be readily understood within the context of the chaotic and rushed training environment and also by recruits from diverse backgrounds, and you really have to work in recruit centers to understand this. It's really a busy sort of loud, noisy sort of environment. You have lots of individuals coming in from all over the United States, lots of different backgrounds; sometimes English is not their first language.

We had to develop a questionnaire that could be answered in this sort of situation by young recruits from all kinds of backgrounds.

This is not -- and I want to emphasize

this -- this is not a research setting. We had to design a program like they design jet airplanes. I mean, we had Ph.D.'s and in this case M.D.'s that designed a program that was going to be administered by people with a high school education.

And so we had to develop something that was relatively simple and easy to administer and that could be done on a routine basis. This is not a research study. It's a routine database.

So we had to come up with questions that were simple and easily understood and it was not a complex survey instrument to work their way through.

In every case that we could, we used validated questions. A lot of these questionnaires with health information are for research purposes and really did not fit the recruit environment, but they did fit the sort of situation we used them.

In particular, the SF-36 was used extensively to measure health status -- which is included in the RAP questionnaire.

And the questions had to be designed not to require immediate intervention because really the health problems of your recruits should have been screened out at the MEPS center, and that's not the purpose of the RAP.

Now, I want to say something about the historical precedent -- as a lot of you know, I spent a lot of time rummaging around in libraries with dusty books, so this is

something I'm very interested in, but I think it's instructive that -- to go through this very quickly as far as the RAP process is concerned.

There's been self-administered questionnaires that have been used to screen recruits, at least since World War I. I haven't found any references before World War I.

But this has been going on for a long time -- over 80 years we had various programs where we tried -- where we administered questionnaires to recruits to collect different types of medical and psychological information. This has been going on a long time.

However, these instruments were used primarily to screen recruits for psychological problems.

And it's interesting -- even going back to World War I, they were effective in identifying groups but not individuals at higher risk of developing psychiatric problems.

You could administer these questionnaires even in World War I -- you could find groups that were at higher risk of having problems of psychiatric -- were at high risk of psychiatric problems during their military service.

But within those groups, most of the individuals did well. Even though they're at higher risk, most of them did well.

So if you screened recruits on the basis of these survey instruments and tossed out the ones who are at high risk,

you'd actually be losing more individuals who would have a successful military career than individuals who would not.

So they were effective at identifying groups but not individuals.

All these programs -- there's been at least a half a dozen of them since World War I -- were discontinued during periods of manpower shortages when the military wasn't as interested in screening recruits when they needed every body they could get.

They also created a lot of controversy, and they were eliminated over time because, when you start denying individuals a chance to serve their country, you raise a lot of political questions -- and brought these sort of screening programs into disrepute amongst politicians and other individuals.

So they really didn't continue for a number of reasons.

None of them were designed to collect baseline health data. As far as I can tell, none of them were conceptualized or designed for this purpose. They were all seen as screening tools.

It's kind of interesting -- I was actually just asked recently why this was true, why none of them were conceptualized this way. I really don't know that answer.

I think one of the reasons possibly is the fact

that the technology has changed.

When I entered the military just 21 years ago, we had no desktop computers. We were using typewriters, and there was no way to readily enter data into a computer database and retrieve that data. That's something very new.

I think it's only now in the last 10 to 20 years have we developed the technology where we can computerize this sort of data and make it available, make it accessible for it to be useful.

Okay, some recent precedent -- as I said, the AFMET program screens Air Force personnel for psychological problems and has some empiric data that really -- the best -- the most accurate answers can be obtained in the first week of recruit training.

There's also -- as I mentioned, the SHIP -- Sailors Health Inventory Project which uses paper-and-pencil questionnaires that are scannable to collect baseline health data -- it's really the forerunner of the RAP program, and then the civilian HMO's routinely collect baseline health data.

And this has already been mentioned -- I'm not going to spend much time with this -- this was first reviewed by FEP in 1997. It was included in the Presidential Review Directive in 1998, endorsed by the ILM in 1999 and 2000 specifically endorsed.

It was recommended by the Presidential Special

Oversight Board in December 2000.

And I'm not going to go through the language of the Presidential Review Directive, but it was said, "Recommend that we institute this."

I'll say something about some of the current issues. I'm not going to go into this 'cause the follow-up lectures are going to discuss this, but pilot testing of the questionnaire and computer software is ongoing. It's been fully established at the Marine Corps Recruit Depot in San Diego -- and the use of the RAP in recruit camps.

This is something we really didn't anticipate when we started this whole program. It really has aided in the recruit process. It has speeded up in-processing in the CHCS, and you know, I've had the opportunity and pleasure to visit about half a dozen recruit centers now to see how they enter their new recruits into CHCS, how they enter them into our health care system, and practically all of them do it in a different way.

Some of them do it in a very efficient way, like in Great Lakes with the SHIP program. Some do it in a very inefficient way.

What the RAP does is offer an automated way to enter this sort of baseline health information needed for CHCS, and it actually speeds up the induction process.

We really didn't anticipate this at first, but

certainly it's been a help in getting this into recruit centers with the RAP program 'cause it aids them in their recruit in-processing.

It also is useful in preventive medicine efforts 'cause it identifies recruits who may need some additional assistance like smoking cessation programs.

Some of the other future issues -- I think we're going to hear from the Canadians today about their work on a baseline health assessment program. It has been reviewed in the United Kingdom and Australia. I don't quite know what the status of their thoughts on the RAP right now are (sic).

The use of the RAP -- is being used by the National Center on War-Related Illnesses -- both the DOD and VA centers. It's going to be the baseline data for the millennium cohort study in the USA, and then the last point -- the one we're here today for -- is the decision is pending on DOD-wide implementation.

Let me just provide you one more quote. This is from the general accounting office, just from this year, January 24th, just a month ago or so, and it says,

> "An effective military medical surveillance system needs to collect reliable information on the health care..."

each of the points -- and it says, "baseline health status and

subsequent health changes." And this says something very important to me.

If the GAO understands the need for baseline health data, then really I think we can --

(Laughter.)

DR. HYAMS: This says something very directly to me.

And it's interesting -- just yesterday I learned that we're going to have another hearing on the 27th of this month about our activities involving the -- our Afghan deployment, what kind of surveillance are we conducting on their health status, and what kind of health risks are they facing, and what kind of preventive medicine efforts are involved in this Afghan deployment?

I really think the horse is out of the barn, so to speak. You know, even though our military troops now are healthier than they have ever been by historical standards and we have remarkably low casualty rates considering the sort of conflicts that we're involved in, we're going to be asked more and more questions about the health status of our military personnel and veterans after they leave military service. We've got to be able to answer those questions.

And so I think the only way we're going to be able to do that is if we have baseline health data and longitudinal health data -- really, a lifelong health record of all of our

military personnel and veterans after they leave active duty.

This is just some of the participants in the RAP developmental program. It's been a collaboration. Most of the work obviously has been done by DOD, but VA's been involved and also HHS.

Questions?

DR. OSTROFF: Thank you so much. Let me open it up to questions from the board.

DR. HYAMS: Let me just say something very quickly. It's very interesting -- just to give another anecdote. When I retired last year, when I went through my retirement physical, I completed again the original SF-98 -- or was it 93 and 98? SF-93 and 88 -- the same form -- the exact, same form that I filled out when I entered the military 21 years before. This is a form that had its origin somewhere in the 1950s or '60s. I never tracked it down to its birthplace.

I mean, I was still being asked whether or not I could see out of both eyes. I mean, that's sort of where we stand sometimes with our sort of longitudinal database.

The physician looking at my responses to this form didn't look at any of my answers at all, only looked at the flags, the little notes I made on the outside about any outstanding health problems, and certainly the physician did not have time or really the capability of taking my original SF-93 and comparing it with the one that I filled out at retirement to

see what kind of health changes had occurred during my military career. I mean, it just wasn't possible.

We really have that capability now, and we should implement it. It will provide much better health care in the future if this sort of data is readily accessible to our health care providers.

DR. OSTROFF: Dr. Runyan?

DR. RUNYAN: You said something along the way that got me thinking -- you said something about some of the people filling out the forms -- English may not be their first language, and I'm just wondering -- I was thinking also about literacy issues and the extent to which you've been able to figure out just how well understood these questions are and do any kind of validation with -- any trial period of developing the instruments to make sure that you're getting what you think you're getting.

DR. HYAMS: Well, I myself am involved in focus groups where we administered the questionnaire or pilot questions to recruits -- real recruits in the recruit setting to see how well they understood the questions and see what kind of comments they had.

It's a real eye-opener for me. The 17, 18, 19-year-olds really have a different view of things than I did at my advanced years, and they use different terminology sometimes.

And it really was very helpful to go through that process 'cause we ended up with really simpler questions,

questions that were much better understood, and so that sort of process is ongoing to try to build the best questions we can.

I think Commander Ryan can answer that also. What has your experience been? You've done some retesting -- or are you going to talk about that later?

CMDR. RYAN: I will have a little bit to say about what we know from the San Diego experience. Some of it is assessed by our test/retest of folks, but it's difficult -- I'm not sure that we know completely whether or not all recruits understand it as completely as we would like them to.

DR. OSTROFF: Has there been any thought to having the questionnaire in other languages?

DR. HYAMS: No. I mean, it's crossed our mind. What do you think, Commander Ryan?

CMDR. RYAN: Well, I mean, there are standards for entering the military that include a basic understanding of English, so we're sort of working from that point forward, and I don't think there's been a lot of thought into accommodating other languages since recruits are supposed to be able to go through their military paces with a basic understanding of English.

You know, it's difficult to get at those questions, but we do get a strong sense from the focus groups and from the test/retest that we are getting reasonably valid, reproducible responses.

At Great Lakes, the SHIP program is interesting -- they have it orally administered so there's a corpsman or a medic who's actually speaking through the survey with recruits as it's done, and that would certainly be possible for recruits who don't have English as a first language or are having problems, and it's actually what's done at MCRD with folks who are having trouble understanding it.

But the concept that Dr. Hyams had was make it so extendable to the basic training centers that it wouldn't have to be orally administered and potentially introducing the biases of the oral administerer (sic) of the survey.

So --

DR. RUNYAN: There are some techniques that have been tried that might be worth looking at to have -- like headsets with the questions that -- the respondent would hear the question from a tape recording while they're filling out a form so that they have both -- you know, the reading cues and the auditory cues, and that that helps, I think, some less -- some individuals who are less fully literate.

DR. OSTROFF: Dr. Herbold?

DR. HERBOLD: John Herbold. I'd like to commend you all on a wonderful program process and -- this is just great.

One observation -- under your purpose slide where you mention "Develop improved preventive medicine strategies, DOD and the VA," you have one example. I think for marketing

purposes this is an opportunity to have a long laundry list hitting both genders, ethnicities, age groups as to things that you can do at different stages of life and for different groups of people.

This is -- you know, one of the phrases that we used, rightly or wrongly, in the '80s was -- for HIV screening was the "walking blood bank," and that just took off as -- that was a phrase that was used.

And so here to -- because as you all realize, this is a cost, a logistics tale, and it's going to have to be sold at every step of a person's career and a value shown.

But, again, my congratulations. This is just great.

DR. OSTROFF: Here and then --

DR. PATRICK: Kevin Patrick. I noticed one of the objectives of this was to speed the process of taking a medical history, and there's been intent here to integrate this with this CHCS-2. Is that beginning to work? Are the data that are collected in the RAP now beginning to be made available to clinicians when they're seeing these people in follow-up in this pilot?

DR. HYAMS: No, we haven't gotten to that place yet. I think Commander Ryan will speak later to the fact that the pilot program in San Diego is totally integrated now with CHCS, but whether or not the physicians have access to it

yet -- I don't know.

CMDR. RYAN: The only value right now to the clinician in terms of CHCS is that recruits get -- in San Diego -- registered in the system, so if they're seen for their, you know, subsequent injury or whatever, they're already in the system; it's easy -- it speeds the general acute care because they're already in the system, but that's not the level that's envisioned in the future where all the data would be in CHCS-2, and Commander Wah's going to speak about that later, about how feasible -- and what the obstacles are for that.

In that case, all of the data would be in a system, and clinicians could see -- you know -- any field that was of interest to them in that automated database.

DR. PATRICK: I see. That's really one of the very exciting dimensions of this, I think, and it's in the private sector as well -- this whole notion of moving into personal lifetime records that follow individuals and that, in fact, are available to them at any point in the care pathway.

And I think it will be important, as we study this over time, to get a sense of kind of what percentage of this CHCS-2 has been completed to date, how well is it working -- I suspect now it's a wonderful, grand architecture as planned, but is it two-percent complete and are we ten percent in another year and 20 percent a year afterwards? Because this whole -- again, these are incredibly complex systems to develop, and -- which the

VA well knows. Of course, the VA is one of the pioneers in developing a lot of the computerized records.

So I think it will be important to ask that question for the board to get periodic updates on the progress of this as it integrates into the substantial -- into the larger system.

Second question -- I note that there's somebody from CDC. Which office at CDC is Dr. Barrett representing?

DR. OSTROFF: She's the person that deals with Gulf War illness and -- Center for Environmental Health.

DR. PATRICK: Okay.

DR. HYAMS: She actually deals with all the deployment health issues, but certainly Gulf War's been a dominant theme in her work.

DR. PATRICK: Well, it occurs to me -- again, others at CDC might have an interest in the development of this -- several of the areas that are involved in surveillance, at least, but also the whole notion of this new initiative in public health informatics because I think there's an attempt to develop and build out a system of public health informatics that will be informed by many of the systems that are really driven on the clinical side to enable at least surveillance as we describe it in our general terms but the syndromic surveillance that others are talking about that are often heavily involved in gathering data from the clinical side of the shop -- the ongoing

care processes rather than reportable illnesses and whatnot.

So I would encourage that we -- the group think of involving someone from that public health informatics -- and then at least some of the initial planning of the architecture of this and the CHCS-2.

MR. FRIEDL: Carl Friedl, MRMC. You mentioned twice that this was not research -- of course, research dollars have gone into this -- and started something like the SHIP program that was totally surveillance, and now we're doing some research studies to try to improve on that and come up with -- you know, it's been experimental in the sense that you're trying to develop the right questions, and you're trying to do it in a systematic way with specific hypothesis testing and looking at outcomes and so on to improve on that old form that you filled out, you know, 30 years ago when you first came in and it hasn't changed.

It's not just subject matter expertise that's going into forming some new questions that we think are about right, and I think, in fact, that's the question you put to the board here today or that Roger Gibson had set them up for.

Are we done with that research phase? Are we ready to implement this DOD-wide, and that's the real question, and that's the transition.

This is another example of what at least three people commented on yesterday as this gray area between

surveillance and research. It's actually fairly clear.

And one of the definitions, of course, is: Are RTD and ED dollars going to it? And if they are and it wasn't researched --

(Laughter.)

MR. FRIEDL: -- then some of our bosses are in trouble for misappropriation of funds.

DR. HYAMS: You know, I overstated the case --

(Laughter.)

DR. HYAMS: -- for a reason. Carl has been one of our biggest supporters in helping us obtain funding for the developmental period of the RAP project. Without Carl, we really wouldn't be where we are now. I didn't want to shortchange him. I do think it's time to shift gears -- you know, to move into programmatic funding and get out of the research stage. This is not going to be a research program. It's going to be a routine database.

If it's perceived as a research program, it's going to have much less utility, and there's going to be a lot of questions raised about why we're doing this. We really need to move on to the operational aspects of this.

I overstated the case 'cause I think it's time to shift gears on this, but I can't -- you know, I can't overemphasize how helpful the research funding has been and Carl's support in the development of the RAP.

DR. OSTROFF: This is a very sensitive issue because, you know, I -- this is part of what I deal with at CDC in making these types of decisions, and you know, I looked through the questionnaire itself, and there is a lot of very sensitive questions in this questionnaire, and you know, seeing it become part of the medical records raises the whole issues about privacy protections and things of that nature and how potentially do some epidemiological analyses that might done for research purposes, how you reconcile that with some of the recent HEPA privacy issues.

DR. HYAMS: Well, I think for research -- obviously, this data will be useful for research studies once we start collecting baseline data on everyone entering the military service.

I think to do research with this study -- just as we do when we use the hospitalization data for research, the researchers will have to have an approved protocol with both scientific and IRB approval, and then they can -- once they have that approval, then they can use the data to do research studies.

So I mean there is a research aspect of this, but I think it will have to be done under protocol. The database itself, though, will be used for routine health care and preventive medicine on a daily basis.

So I think that's how we'll separate most of that out.

MR. FRIEDL: Yeah, I wasn't looking for credit for support for the RAP. This has been mostly your initiative, I think, from the beginning.

But really to keep things in sort of the right blocks here -- because it determines when we have to go to human use, and that's always a bone of contention because they're pretty strict these days and for good reason -- I mean, we have to do that.

In research, we have to be aware of these sensitive questions that cause all sorts of problems, and we've seen plenty of examples of those where we thought this was just a dotting the I's and crossing the T's.

But, you know, this -- if this does move to surveillance and DOD-wide approach, that doesn't mean we won't still be doing research.

DR. HYAMS: Right.

MR. FRIEDL: But it'll be funded differently; it'll be handled differently. That'll be a routine of care there, and then we still come to -- we have to use these surveillance databases to do a lot of our research, and that calls for research protocol and that's research-funded, and we tap into them routinely.

Colonel Hoge does that with some of the CHPPM databases now, and that's fine.

So we just have to be clear on, you know, when

something is transitioning and it's become sort of the standard of care as opposed to it's still experimental.

DR. HYAMS: Let me just say about the sensitive questions. We haven't decided on our final questionnaire. I mean, we're still evaluating it, and we've actually removed some questions that we thought were too sensitive after we'd done some pilot testing, and we may remove additional questions. We're just going to have to see how it works out 'cause we're still evaluating all of these questions.

So kind of keep that in mind. I think there are some sensitive questions in the RAP questionnaire, but there could be even more sensitive questions that could have been included as well.

So it's still a process we're working on.

DR. OSTROFF: Let's go to Dr. Berg, and then we'll go to Chuck.

DR. BERG: Bill Berg. As someone who has personally filled out an 88 and a 93 on occasion, I agree with your assessment.

I think there's a question, "Have you ever had venereal disease?" "Do you drink alcoholic beverages?" I would like to compliment the group mightily for the detail it gets into here on things that are truly preventive-oriented such as violence, substance abuse, anger management -- I think this is a quantum step forward in terms of the type of information that's

being collected that can be truly useful in a variety of preventive medicine ways.

And I hope that the questions don't get whittled down too far. I realize you're still validating this, and if people aren't going to answer it, it's not a useful question, but I -- this is on the cutting edge of preventive medicine in many of the areas that it's getting into here.

DR. HYAMS: Thanks, Bill.

MR. ENGEL: Chuck Engel, Uniform Services University. I just wanted to comment on the sensitive question issue, and I know Craig has read this recent book by Ben Shepherd on The History of Military Psychiatry in the 20th Century. There's a section in there that goes into screening as it pertains to psychiatric illness, and one of the themes that comes through -- I think Craig touched on it in his talk, but to me the central theme that came through is the undoing of a lot of this sort of -- you know, we call it surveillance now -- they called it screening back then -- is that the public looks in at the questions and practices, and they think that it's unacceptable, that some of the things that get asked are unacceptable, and he gives a lot of interesting examples which currently would seem really outrageous, but I think probably at the time to the people doing it, it didn't seem so outrageous.

So my -- to pull all this together, what I'm really suggesting is that I think piloting of this has to include

piloting with the general public -- 'cause, you know, if there comes a time when the general public feels that people are being turned away from military service based on findings of this questionnaire, this questionnaire will come under intense scrutiny by the general public.

And if there are questions on this that they find, you know, unacceptable, it could be the undoing of the whole process. Historically, it has been the undoing of the whole process. This is not a new idea. It hasn't happened for important historical reasons. Part of it's technology, but part of it is, I think, some of the mental health domain questions.

Believe me, I'm an advocate of trying to ask those questions. My main message is we have to ask them in ways that are acceptable to the general public.

DR. HYAMS: Let me just say one of the biggest issues in World War I was nailbiting which was considered a reason for denying military service. That's one of the older ideas.

I think Chuck's right. I think there's a difference, though, between using data from a question to deny someone the chance to serve their country and using that data to aid your efforts to provide health care and preventive medicine while a person is in the military and after they leave.

I think it's a different sort of take on the question.

I think in one case you would have trouble asking the question, but I think, when the questions are being used for better medical care, I think they will be more acceptable to the general public.

DR. OSTROFF: We're going to have to try to keep on schedule and move on.

The next presentation is Dr. Page from the Institute of Medicine. We thank you for being here.

DR. PAGE: Good morning. I'm glad to be here to address you. I will be talking about research. It's the sort of thing I do.

I'm with a medical follow-up agency in the Institute of Medicine.

You've seen these words before, but I need to put that up to tell you IOM's involvement in this. It's the 1999 IOM report.

The strategy is to protect the health of deployed U.S. forces, and there's a recommendation regarding RAP -- implemented to collect baseline health data from all recruits.

We prospectively test hypotheses about predisposing factors, development of disease, injury, medically unexplained symptoms.

Now, what I really do is not the sort of IOM study. I'm a researcher in one of the few places in the National

Academy of Sciences that actually does research, and up until recently the World War II was still big business with us.

One of our longest studies, one that I've been involved with, is the study of history of the health of POW's of World War II and the Korean War.

So what I want to tell you a little bit about today is about that study and baseline data and how we didn't have it and how we might have used it.

The most recently completed study is based on a 50-year follow-up, one of the few 50-year follow-ups I know about. We have alternated mortality and morbidity follow-ups through the years. There have been seven follow-ups in sequence.

We found an excess of deaths due to heart disease, liver disease, melanoma and Parkinson's Disease.

But the earliest morbidity study showed that psychiatric problems were the most prominent in long-term health effects of military captivity.

Some of you may know there were somewhat in the neighborhood of 130,000 POW's in World War II, most in the European theater. We have separate, independent samples of European, Pacific and Korean prisoners.

The risk factor studies, however, were handicapped by a lack of baseline data.

When we began these studies, of course something like PTSD, posttraumatic stress disorder, did not exist as a

diagnosis. We did, however, study depressive symptoms which is one of the co-morbidities, and we found a risk of depressive symptoms 40 years after repatriation -- was affected by what we call buffering factors: age of capture, high rate of capture, less chance of PTSD; years of education, higher education, less risk; marital status, married, less risk of subsequent PTSD.

But these are probably only proxies for the true underlying buffering factors, whatever they might have been, and we didn't get a chance to measure them.

Similarly, in the latest mortality study, we found that cirrhosis mortality was increased in the former POW's, but we couldn't identify any clear risk factors.

We had ancillary data collected 40 years after the fact on the alcohol use, and that was probably not a factor. Actually, these rates of drinking are lower in the POW's, surprisingly.

But hepatitis might have been a factor; however, we didn't have the baseline data for the individual POW's, and so we could not speculate -- we could only speculate about the possible roles for these potential risk factors.

So that's sort of the story on baseline risk factors, and now I'm going to switch gears just slightly and say that there may be ancillary benefits, collateral benefits, as I call them here.

I'm also the director of the NAS twin registry

which is a registry of World War II twins. There are some 16,000 pairs originally in the registry, and we've published now more than 200 papers in scientific journals on subjects ranging from schizophrenia to heart disease and Parkinson's Disease and Alzheimer's and that sort of thing.

We have undertaken a pilot study, something we'll call the Current Era Twin Registry, a project taken in collaboration with the Army medical surveillance activity. We wanted to investigate the feasibility of an active twin registry in the current military population.

The volunteer rate of contacted twin pairs was greater than 95 percent, but the cost of identification -- contacting, registering, was $180 per twin pair, and my boss, a former Army colonel, says that's too high, so -- what we have done is asked the question, "Are you a twin" -- be included in the RAP. Now, that makes things a lot more efficient and cost-effective.

I can tell you -- I won't say much now unless there's questions -- that the potential value of twin studies at DOD remains high, even in the genomics era.

The classical twin study compares identical twins with fraternal twins and looks at the correlation of outcome traits in these two, and based on just those simple measurements, we can make some estimates of heritability and the genetic influence on -- well, as you heard, many, many traits.

So that concludes my presentation, and I'll take any questions or comments.

DR. OSTROFF: Thanks. That's a fascinating presentation. Let me ask if there's any questions from the board, and I'll just point out that we're going to have to try to speed up the presentations, and so I'll just try to take one or possibly two questions from the board members right now.

DR. HERBOLD: John Herbold. Bill, you mentioned yesterday that there's a website that lists all the registries and studies that the medical follow-up agency has been involved in. The board might be interested in using that.

DR. PAGE: I can send that site to Rick.

DR. OSTROFF: Is there a question?

(No audible response.)

DR. OSTROFF: Thank you so much. I think -- Commander Ryan, return performance.

(Pause.)

CMDR. RYAN: Well, thank you. I'm privileged to work with Dr. Hyams and the Recruit Assessment Program project for the last few years, and I'll give you a brief update on what we've done out here in San Diego.

I won't reiterate this -- of course, collection of baseline data has been considered essential for understanding how -- what people look like when they come in, how service-related exposures might affect their health and whether we can do

early intervention or prevention programs based on some of this baseline data.

So what we did in San Diego was we wrote a protocol, and that's because we're a naval health research center, so we really have to do everything we do under research protocols.

We wrote a protocol for the pilot project to implement Recruit Assessment Program at Marine Corps Recruit Depot San Diego in February 2000, so two years ago, actually, and we put that through an IRB, so again I'm touching on the sensitive issue here about surveillance and research. But that's the paradigm we have to operate under at Naval Health Research Center.

So we put this protocol through the IRB at our own research center, and it was interesting that after -- the IRB, both scientific review and human use review, had no trouble supporting the concept at all but struggled quite a bit with the question of research, consent and so on.

Our IRB which responds to BUMED, the Navy Surgeon General, considered the project exempt from consent requirements and the Privacy Act to be adequate in terms of permission for recruits to complete the questionnaire.

The IRB at Naval Medical Center San Diego which has oversight over the Marine Corps Recruit Depot -- so this is another IRB -- it's actually another IRB reporting chain that we

went through with this same protocol -- considered the project -- this was their term -- surveillance, not research -- still reviewed it, still supported it, but it was sort of the same bottom line that came out of the NRHC IRB review which is no consent will be required.

Now, both IRB's continued to review the project annually because it's an IRB protocol, but they have considered the protocol under this domain.

After going through the IRB process, our next large hurdle was getting acceptance at the Marine Corps Recruit Depot, and this is actually -- and you got to see them yesterday -- this is a tough crowd.

I've been to most of the recruit centers in the United States, the ten recruit centers, and I consider MCRD San Diego probably the toughest crowd.

They really are very appropriately protective of recruits and recruit time, as all the basic training centers are.

This is a very tough group to sell on doing any projects that would at all put a ripple into the basic standard of -- standard procedures that they had for in-processing.

So we had to really prove that the RAP program would not interfere with the usual in-processing and, in addition, had to add timesaving steps so we had to show value.

So all the concerns about needing baseline data and wanting to do good preventive service and wanting to know

what people's deployments, how deployments would affect their health, and these questions about prisoners of war and so on -- they did not fall on deaf ears, but the MCRD said, "We still will not embrace this unless you show us that you'll add value right here at in-processing."

So we had at least 12 formal meetings and numerous, numerous informal meetings with all of the stakeholders at Marine Corps Recruit Depot over quite a prolonged process to sort of ingratiate ourselves into that environment, and it was a good experience.

We were able to do focus groups with recruits beginning in 2000 and early 2001. The original survey that Dr. Hyams and others had worked on was longer -- was about 17 pages and took about 60 minutes to complete. We honed that down in focus groups to an 11-page survey that took 25 minutes to complete. About 20 to 35 minutes was the range.

And, again, the questions were revised mostly for simplicity -- to make them as simple as possible.

There's still improvements planned in conjunction with -- right now with our Army colleagues who are working at Fort Jackson.

There are no women at Marine Corps Recruit Depot San Diego, so we weren't able to pilot the women-specific questions which was certainly an important feature.

Now, what do we do to sell this to make the Marine

Corps Recruit Depot accept the process? This question about CHCS registration is the way we sold the RAP project. All recruits at the -- historically at MCRD San Diego have their demographic data hand-entered into the CHCS system -- that's the composite health care system that just allows general medical care in the local area network. Each CHCS is a local area network in the military treatment facility, so all their prescriptions and all their laboratory work and all of their care visits are recorded in the CHCS system and have to be registered to even be able to have that care initiated.

And so that was all being done by hand, right at in-processing and was quite time-consuming. We said, "Wow, we'll have demographics as part of this database; why don't we just link these demographics into CHCS and zip, automate the registration, and we'll save you lots of time."

And they loved that idea. Of course, it's not that easy to do. Great Lakes was able to do it years ago with the SHIP system but was not able, unfortunately, to reproduce how they had done that.

(Laughter.)

CMDR. RYAN: The folks who had created that link -- CHCS is very unique sort of software system with mumps programming -- you know, it's not a tough code to crack. I don't understand how those fields get filled, and Great Lakes unfortunately was not able to retrace their footsteps and tell us

how that linkage had happened. It works at Great Lakes, but they weren't able to reproduce it for us at MCRD San Diego.

So we contracted with a group called Integic, and they use -- it's a software system and AMOBJICS (ph) and -- I only know enough to be dangerous to say the words that actually allowed the connectivity of a database that ours is maintained in that standard -- Access system -- Microsoft Access system to the CHCS system and automate mini-registration which allows recruits to begin their medical care at the Marine Corps Recruit Depot.

And that was actually quite a process to get approvals and so on, to get that to work.

But we ended up being quite successful, and it works.

What happened with that is that we now have mini-registration of all recruits into the CHCS system, and it saves at least one FT -- at least one full-time person, probably more than that, at the Marine Corps Recruit Depot. So, of course, the clinic staff is delighted and actually -- they sort of regrooved that FT, if you will -- that FT quickly assumed other jobs, and I remember that -- about a few weeks after RAP had started there was concern that there would be about a week where we wouldn't be able to do the mini-registration, and the Marine Corps Recruit Depot said, "You can't do that; that's not possible. Nobody can hand-enter these recruits in CHCS," whereas it had been less than a month that that person had been hand-entering recruits into the

CHCS system.

That person was already gone. They had already begun relying on the RAP system to automate that registration.

Other things that are nice side effects of this -- when recruits are seen for care, of course their care is speeded up because they don't have to wait to have the registration done, and we can create some standard forms. This is really simple stuff, but you can create standard laboratory forms, much as Great Lakes does, that speeds some of the processes that recruits go through.

It's sort of sad to see, in this day and age, recruits hand-entering their name and SSN on a million pieces of paper at in-processing, and we can automate that just by connecting that database to whatever forms need to be filled out.

Now, there's a little footnote there at the bottom that talks about data quality being improved in CHCS. This is something that I don't completely understand, but the folks at the hospital -- at the Naval Medical Center San Diego who have purview over the CHCS system here locally were quite concerned about us messing with the CHCS system.

Even though the end product is still 25,000 registered recruits, they were quite concerned that, when we automated that, we might somehow mess up the data.

It turns out that the data are actually quite improved and that synchronization of records to DEERS is now 100

percent where previously it was less than 50 percent, and the folks in the basement of the hospital who run the information systems are delighted with this outcome which is also nice for us, even though, again, it's not something that I think any of us understood about DEERS synchronization, though Commander Wah may be able to speak better about those things, Commander Wah having CHCS expertise.

So where are we right now? Well, we're off and running. Those are our recruits at MCRD San Diego.

In June 2001, all recruits began being automatically entered and having all of their RAP data filled out on our original RAP survey which we are maintaining the data from in a large Access database that we maintain securely locally at Naval Health Research Center.

The other nice outcome of this is the relationship between the Naval Health Research Center and Marine Corps Recruit Depot was actually strengthened through all of this process because they have a natural -- probably justified -- suspicion of researchers getting into the basic training center, and this relationship was a nice outcome, that the Marine Corps Recruit Depot actually -- saw a nice product from the relationship and feels like they're contributing to this important RAP program.

I'm not going to speak about where we are today. Commander Young has done a wonderful job assuming ownership of the Marine Corps Recruit Depot project for us and will tell you a

little bit more about what we've seen particularly in those data in the first six months or so of implementation.

DR. OSTROFF: Thanks. Let's move on to Commander Young.

CMDR. YOUNG: Good morning. It's been my privilege to join the staff at the DOD Center for Deployment Health Research this past October and to be able to speak to all of you about the implementation of the Recruit Assessment Program at MCRD San Diego.

As anyone with experience with boot camp knows, recruit in-processing also involves long waits in lines.

The RAP questionnaire can be completed under a variety of circumstances.

RAP does not need to be administered by trained personnel. The drill instructors pick up the questionnaires from our staff, and sometime in those first few hours after the recruits come to MCRD to the receiving area and before they have to start in-processing at the branch medical clinic the next morning, they fill out these surveys.

The questionnaire is short enough not to interfere with the business of making recruits into Marines. It takes 25 minutes to fill out.

As I said, the drill instructors then turn in stacks of questionnaires to our staff which consist of 1.5 full-time equivalent workers and here you see the .5 about to --

(Laughter.)

CMDR. YOUNG: -- questionnaires with the industrial strength paper cutter.

They scan -- we take care of 400 to 500 questionnaires a week.

Here the despined (ph) questionnaires are being scanned.

In here, the questionnaires are being verified.

Before I get into some of our frequency data, I want to let Dr. Page know that we do know that 2.3 percent of our recruits say they are a twin, a triplet or one of a multiple birth set.

Ninety-one percent of the recruits are born in the U.S. This slide shows where the remaining nine percent born, with three percent coming from Mexico, 1.5 percent born in Asia, 1.2 percent Central or South America, another one percent in Europe.

Our original questionnaire listed separately the United Kingdom and the Republic of Ireland, and in our new revised survey we've combined it all as part of Europe.

The Pacific Islands, Canada, the Caribbean and Africa all account for less than one percent, and the category "other" accounts for one percent.

This shows a racial ethnic background with 64 percent being Caucasian, another 22 percent Hispanic, six percent

African-American, three percent Asian, two percent Pacific Islander; two percent Native American or Alaskan Native.

As of September 28th, we changed our coding. We initially could only take the coding for one race, but as of September 28th we accept the coding for multiple combinations, and we're finding that one percent of our recruits are multiracial with various combinations.

This slide shows the furthest educational level of our recruits. Less than one percent have less than a high school education; 2.6 percent have received their GED; 77 percent have a high school graduate diploma; another 18 percent have some college; 1.3 percent graduated from technical or trade school; .5 percent graduated from a four-year college or university, and what you don't even see at the bottom is the four recruits out of the 12,816 who have completed a master's or higher postgraduate degree.

This slide shows the response to the question, "During your last year of high school, how many sports or organized physical activities did you participate in?" Nearly 40 percent marked "none", and then 28 percent one, 21 percent two, and nearly 13 percent three or more.

Questions like this are of interest to MCRD where stress fractures are a common problem, and so it will be interesting to correlate questions like this.

Our Army friends at CHPPM also suggested that we

add another question asking for how much weekly aerobic, sports or physical activity do you participate in, and we added this question in the new version of the questionnaire.

Let's see -- these are more examples of RAP data from MCRD. One third of recruits say they have had no alcohol in the last year; 87 percent say they have never driven a car after drinking alcohol; more than 60 percent say they are nonsmokers; more than 60 percent say they have used condoms the last time they had sex, and 60 percent say they always wear seatbelts when riding or driving in a car.

Judging from this slide -- the antitobacco groups are not doing too bad of a job of discouraging cigarette smoking. About 60 percent of recruits say they have never smoked regularly. Of the remaining 40 percent, we see that nearly 30 percent have had their first cigarette before age 18, five percent by age 13, another nine percent by age 15, a big increase in those problem years of ages 16 and 17.

Then it goes down between 18 to 20 -- and at 21 or older it's one percent.

In contrast with the previous slide on tobacco, this slide shows age of first alcohol drink. More than 60 percent of recruits have had alcohol before the age of 18 with nearly 13 percent by age 13, another 19 percent by age 15, again a big jump in those problem years of ages 16 and 17, decreasing as they get older, and 19 percent of recruits say they have never

had alcohol.

This is a question that might be useful in determining the numbers of recruits that may be at risk for alcohol problems. The question is: "How many times do you have six or more drinks at one sitting?" Sixty-nine percent responded, "Never." Twenty-four percent responded, "Monthly." Seven percent responded, "Weekly," and .6 percent responded, "Daily."

In another question on the survey, 13.8 percent of recruits say that they have a biological mother or father with an alcohol problem.

So alcohol use is definitely an important data that we want baseline data on.

On the same lines of asking about first tobacco and first alcohol, the survey asks about age of first sexual intercourse. This chart mirrors the one before on first alcohol with more than 65 percent of recruits having first sexual intercourse before age 18, more than seven percent by age 13, another 22 percent by age 15, and another 36 percent again in those problem years of ages 16 and 17, decreasing as you get older.

Like 19 percent of recruits have never had alcohol, 19 percent of recruits have never had sex.

Besides the sensitive questions on sexual intercourse, the questionnaire also asks sensitive questions on

family dysfunction.

Over 42 percent of recruits come from families of divorce. Although two thirds are raised by two parents, a third are not. More than a quarter of our recruits are raised by one parent, two and a half percent by a grandparent, and the remaining three percent are raised by either other relatives, foster parents or guardians or other situations such as in group homes or institutions.

More than five percent say that growing up they felt mistreated emotionally; more than three percent say they felt mistreated physically, and more than one percent experienced sexual abuse.

This graph shows the completion of survey questions from the beginning to the end. The first drop that you see below the 90 percent mark is related to the work history series of questions. That's in Section 3, question 2, where they are asked if they had exposure to dess (ph), fumes, asbestos, insecticide, ionizing radiation.

The second level drop is for the "Are you left-handed, or are you right-handed" question. I'm not sure why that is, but we decided to add the option "both" on the new version of the questionnaire in case we're missing the ambidextrous recruits.

The next big drop that goes all the way down there is for the longest question on the survey which is in Section 5,

question 6, and that's the one asking, "Have you ever had trouble with any of the following in your entire life" and lists 23 options.

In the new version, we've reworded the last option from "I had no trouble with any of the above" to "No, I have never had any trouble with any of the above," and we're just hoping that they notice it more and check that off rather than skipping the entire question.

In the last drop that we see -- for the last two pages of the survey -- it's hard to say if the recruits are tired at this point or if they want to avoid answering the sensitive questions that we ask about family dysfunction and physical, emotional, sexual mistreatment in this section, but we've changed the format of the last two pages of the questionnaire in our new version, and we look forward to seeing how things go with our new version of the survey.

Wow -- the yellow really shows up here. This graph is a graph that shows CAPA (ph) statistics, retest statistics. It's different from the one in your handout, and it just shows you that we're keeping our stats folks busy with these analyses. They've done three analyses so far.

The one in your handout shows the CAPA statistics for the 47 recruits in platoon 1037. They're the recruits that we have photos taken of at the beginning of my presentation.

We wanted to have surveys to do test/retest

statistics, and we also wanted to have photos of them actually taking the survey since the DI's have the recruits do the surveys and we don't even seen them normally taking the surveys anymore.

So your handout shows their CAPA's for the various sections of the survey.

The overall CAPA statistic has been .84 in your handout, and that's strong.

In other analyses, we've had CAPA's even closer to one.

To summarize, a lot of these points have been made before. We fully integrated RAP as of June. The drill instructors provide RAP with minimal destruction of training. The initial test/retest results look strong.

I like to end with this slide which is one of the signs at the branch medical clinic at MCRD for those who missed the tour or missed seeing this sign at MCRD.

I'd just like to say that the Marines are very strong on suggestion. The boot camp of today is kinder and gentler probably than boot camp of old, but as MCRD San Diego and a few of the Army boot camps are the last of the all-male boot camps, they probably are closest to the traditional boot camp, and change is not always a welcome thing, but RAP has been embraced at MCRD San Diego. It has been successfully implemented, and I think it is feasible to be implemented at other recruit training centers, and that's all I have to say.

DR. OSTROFF: Thank you for doing a tremendous job. I'm sure it wasn't the easiest of circumstances to get this up and rolling.

Why don't we take one or two questions, and then what we're going to do is we're going to take our break a little earlier than on the schedule, and then, when we return, we're going to shift the schedule around a little bit and break the presentations and have the good Dr. Grabenstein give us his update.

DR. SHANAHAN: Dennis Shanahan. Although this may become clear to me by the end of the day, I'd really like to throw out a general background question, and that is -- I'm very impressed with RAP, number one, but I think it's basically as good as the continuing surveillance program.

I'm having a little trouble understanding how all this integrates together over a long-term surveillance, particularly with the comment CHCS is a local program, and how does this kind of thing interfere with DEERS because clearly the objective is to follow the recruits through their military career and perhaps even beyond. So I'd like to know in general terms how that integrates.

The second question I have is: How are we going to be capturing officers?

DR. OSTROFF: I guess maybe I can comment that, when we have some of the subsequent presentations, it might be

quite a bit clearer than it is, so maybe we can hold off on that point.

DR. POLAND: What is the reading level required to fill this out, and what is the range of reading levels in the recruit accessions?

CMDR. YOUNG: That's a good question. We think they've been having no problems, really, with getting through it. Can you help?

CMDR. RYAN: To get in the service, it's supposed to be minimum sixth-grade reading level, and this is supposed to be a sixth-grade reading level survey.

You know, you might look at some questions and debate that, whether or not that's truly sixth grade, but as near as we can tell, that's what we're aiming for, and again you're supposed to be at the sixth grade reading level to come in the service. I think there are probably exceptions to that rule as well, but that's supposed to be the minimum requirement for anybody to be even sitting in front of us.

DR. POLAND: One other thing -- it wouldn't matter at all to the person taking the survey, but because this survey will get shown in a variety of venues, there are numerous grammatical errors throughout the survey that might want to be corrected.

DR. OSTROFF: One more question.

DR. CLINE: Barney Cline. Has there been any

thought given to testing/retesting on an anonymous basis to get at some sense of reliability to responses -- to particularly the more sensitive questions?

CMDR. YOUNG: Our tests/retests have been -- have not really been a formalized sort of a process. As I kind of mentioned with the group that we took photos of, it was an opportunity for tests/retests.

Other testing that we have done has happened when the DI's were rushed for some reason and the first set of questionnaires weren't completed, and then we haven't retaken it again where they had more time to complete the questionnaire.

I think it's something we could consider, though.

DR. OSTROFF: Let me just have Commander Wah make a comment, and then we'll take our break.

CMDR. WAH: Thank you very much. I'm Robert Wah from the TMA Information Management Directorate. I just wanted to take a moment to answer the question about CHCS-1 and DEERS and also use this as sort of a teaser to make sure people stay for my talk.

(Laughter.)

CMDR. WAH: People mentioned CHCS-2 a number of times, and CHCS-1 is much different from CHCS-2, so I'm just going to talk about CHCS-1 very quickly.

When you talk about using the RAP to integrate into CHCS-1, all they're doing is doing a mini-registration which

is the demographic information about the recruit -- name, rank, serial number, address, and stuff like that.

CHCS-1 is an order-entry results-retrievable system. It isn't really a clinical record other than the fact you can put their prescriptions in, order their labs and get the results back from that.

So it's not a full integration for medical records other than the fact that it saves them time to be able to insert this demographic information so they can begin doing the order entry and results-retrievable immediately. I just wanted to make sure that was clear.

DEERS is the eligibility system that the military uses to make sure people are eligible for everything from health care to commissary privileges, and that is a whole 'nother topic of discussion, so that question I'm going to have to answer offline, but I wanted to make sure it was clear that people understood, when they talk about integrating RAPs with CHCS-1 at MCRD, what they're doing is entering the demographic data into CHCS-1, not the clinical data.

As far as CHCS-2, stay tuned for that.

DR. OSTROFF: Thank you. We're going to go ahead now and take our break, and let's try to be back promptly at 9:15, and we'll get back into the program.

(A break was taken.)

DR. OSTROFF: Colonel Grabenstein, sometimes I

think we should give you frequent presenter points or something like that. But it's always good to see you and always good to hear from you.

LT. COL. GRABENSTEIN: I appreciate the invitation to come back and present. I had occasion to revisit some of the presentations we did for the ACIP and the AFEB in the fall of '99, and they were data-driven; they had lots of numbers on them. They did not have very many years, volumes and page numbers of publications, and one of the delights this time is going to be to show you a series of those.

I'm not going to talk about -- obviously, since the board last met, we've had the outbreak -- the Anthrax attacks along the Eastern seaboard, and I'm not going to dwell on HHS's predominant role in dealing with that, but I do want to talk about -- in very short order -- the use of the Anthrax vaccine, the offering of the vaccine in December in the Hart Building for the postal workers and the others, the AMI building in Florida and the other sites.

And just to summarize it on this slide, this slide has one set of data and a whole lot of speculation on it, which is rather emblematic of where we were back in December.

This red, solid line is the data, and it comes from a Rhesus monkey challenge study back in 1956 where the monkeys were exposed to about 100,000 spores, roughly two LD-50's, and then there was tracking of the residual spores in their

lungs.

And as you can see, at day 60, there was very little, and this is one of the pieces of evidence that went into the 60-day antibiotic duration policy.

I have -- this is a logarithmic graph, and I'm not attempting to lie with statistics -- this is the same data on the linear graph.

But then lo and behold we came to understand the Canadian letter-opening experiments in Suffield, I believe -- or Sheffield.

DR. WHITEHEAD: Sheffield.

LT. COL. GRABENSTEIN: Sheffield -- thank you -- Canada -- which suggested that the opening of an envelope that a person might be exposed to as much as 3,000 LB-50's, and so, if you assume parallelity and you assume that the monkey data applies to humans, you can get these dotted lines.

And so the issue -- of course, in December -- was at the 60th day, if the exposure is that much higher and those "if's" apply, then how many residual spores are in the lungs of these people?

And the other symbolic aspect of these parallel lines is, I think, that, even within a building, depending on how close you were to that envelope, you could have had a variety of exposures to the spores.

So I was confronted with or enraged by the

newspaper headlines calling the offering of the vaccine experimental, and so we developed this slide, and so -- you know, is the use of the Anthrax vaccine -- is Anthrax vaccine licensed was the what we called the pivotal question, and we said the simple answer of yes, it was licensed in November of 1970, but to get to the fuller story of some uses, some products, some ways it's licensed and some uses, some products, some ways it's investigational, we developed this matrix.

The pre-dose use of the vaccine, six dose -- pre-exposure use of the vaccine, six doses licensed, post-exposure, three doses off-label investigational, but not experimental in the classic scientific sense.

At the time in December of '01, the renovations at Bioport (ph) had not yet been approved, so at that day, that month, Bioport's facilities -- the use of product from those facilities was investigational, but as you know -- or as I'll show in a minute, in January the FDA approved those renovations, so we're back over into this column with the facility.

And then the -- each lot is released one by one -- lot FAV-603 was what was offered to the congressional workers, the postal workers and the others.

In December, it was an investigational lot because it had not been released by the FDA, but that same lot in February of '02 is a licensed release lot as far as that goes.

So the many steps to getting a vaccine, a vaccine

manufacturing plant and a vaccine process approved by the FDA -- this chart did not used to all be checked in, and there have been a variety of steps that have taken quite a long period of time to get accomplished.

But we now have the revised potency test, FDA's standards, the renovations in -- in Lansing at the manufacturing plant itself, the contract packager and filler, Hollister-Stear (ph) in Spokane, these post-marketing commitments are the extra SOP's, the extra data that the FDA is asking that be fulfilled, and both parties have agreed to.

Stability studies, revised package labeling, and release of the exhibit or consistency lots -- that last bullet goes to -- I use the term, "The proof is in the pudding." In order to get your plant approved by the FDA, you have to show that you can produce three consistency lots, and that's what has been released by the FDA.

I believe I've shown this slide before to you. These are the independent reviews by civilian physicians and scientists of the safety and effectiveness of the vaccine.

It's here this time to show that we are about to change the color of this bottom bullet with the impending release of the Institute of Medicine report that began back in October of 2000.

These are the members of the Institute of Medicine Committee to assess the safety and the effectiveness of the

vaccine. I suspect many of you know them personally. They are quite eminent scientists.

The committee met in four public sessions -- October, January, April and July. They had a closed session in November. They decided, as I understand it, at that point they did not need to hold further meetings and so decided to begin their report-writing and review process.

Their final report is finishing review now, and we expect that it may be publicly released in the early part of March.

I don't know the contents of the report. I do know from having attended each of those public forums that they asked questions very much like the questions that you all have been asking but many more of them, and many of the same questions we've asked ourselves. We think that the approach that they've taken has been quite consistent with the approach that we've taken in searching for evidence-based indicators of the safety and effectiveness of the vaccine, so we eagerly await their report.

This is the litany -- with the years, volumes and page numbers attached.

There was a handout, a 32-page handout with a one-or-two-page synopsis of each of these safety studies, and you see the title here -- the title here on the left axis or left margin -- the number of vaccine recipients, let alone -- ignoring

any control groups or placebo groups for the particular studies, and then the publication status.

We're grateful to the editors of Vaccine for accepting quite a series of these. We have preliminary reports from Tripler (ph) in Korea in the UMWR, and there are full manuscripts being prepared as well.

The Anthrax vaccine expert committee which reviews the VARES (ph) reports has had its publication or its first year's work accepted in Pharmacoepidemiology and Drug Safety, a variety of other manuscripts in progress, but we're making great strides in getting the -- getting this data into the peer review literature.

I don't have any twin studies among those, so if anybody has any data sets involving twins, we'd be happy to enter them into the collection as well.

(Laughter.)

LT. COL. GRABENSTEIN: One of the studies I'm kind of pleased with as being a little bit novel is an analysis of flight physical examinations at Fort Rucker -- that are housed at Fort Rucker, Alabama. This is the periodic flight physical examinations, long or short, from every Army air crew member -- helicopter pilots, primarily, and their professional colleagues, and so one of the analyses is a matched pairs analysis of 3,300 vaccinated air crew and another 3,300 unvaccinated air crew matched on age, gender, and other factors.

And we found, based on each of the parameters that you see here, physiologic parameters, no difference between the vaccinated and the unvaccinated groups.

These are essentially the easy quantitative data that was most readily available, and we'll continue to delve into this database in even greater detail over time.

We have -- as many of you know, there is an effort underway to evaluate a change of route of administration of the vaccine from subcutaneous to intramuscular, reduction in the number of doses from a six-dose series to perhaps five, perhaps four, perhaps three doses, and a change in the booster dose interval from one year to perhaps two years or three years. This is a double-blinded, randomized, placebo-controlled trial of about 1,600 volunteers.

Dr. Poland may wish to -- has been on more of these conference calls lately than I have been, but his is one of the sites here at Mayo Clinic.

They have added an additional site, I think, since the last time I presented to you. They've added the University of Alabama at Birmingham, recruitment of the first volunteers expected next month, and then it's a 43-month study from the standpoint of the individual volunteers with the final data being collected in late 2006 or early 2007. And I think I've covered that as well.

There's also -- there are animal components to

this group of studies that will involve -- establishing what the clinical correlative protection is in a variety of species that we hope to correlate to humans.

These are the studies that continue, and so we have the dose-reduction route change study. The AVAC (ph) continues its work. It's now up to about 1,800 VARES reports reviewed.

And what's been interesting, I think, in following that process is each of the cells seems to grow arithmetically as more reports are reviewed, but the character or the conclusions reached upon the review has not fundamentally changed. They have their eyes wide open, of course, but it has been effectively more of the same.

Reproductive outcomes, we continue to research. Naval Health Research Center has a project underway with its birth defects registry.

We have a project looking at the wives of vaccinated men from the Center for Health Education Studies at Fort Sam Houston, and we are developing what we call a women's health database project focused on Walter Reed to get essentially every gynecologic and obstetric visit and a wide variety of lab tests and what have you all into one integrated dataset to which we can apply immunization data and assess as well.

A set of long-term retrospective studies -- the one I'll mention is an effort at USARIEM, U.S. Army Research

Institute for Environmental Medicine, looking at their discharge -- disability discharge database using the -- what they call the Tate-Hodd (ph) database.

The preliminary report shows that the odds of an Anthrax-vaccinated person developing a -- or receiving a disability discharge is one fifteenth that of unvaccinated people.

That's the preliminary data. We've got some more selection bias ruling out to work out. We don't have the playing field quite level there, we don't think, but no indicators of -- perhaps more meaningful is that the list of reasons for discharge are not fundamentally different from the two groups. That is perhaps the more meaningful preliminary finding, but that work will continue at a proper pace.

We have several prospective studies underway involving the Army Medical Surveillance Activity, NHIC, Fort Rucker and NHIC again with the millennium cohort study as we've referred -- various people have discussed previously.

And then, at the FDA's request, we are going to perform some serologic studies to look at whether the deferral of Anthrax vaccinations during this vaccine drought that we just went through markedly affects immunogenicity with respect to -- in contrast to the standard dosing schedule.

So with the help of our colleagues at USAMRIT (ph), working on the design for that and at this point we're

searching for the proper site to conduct the project.

So where are we now? This is the current status of Anthrax vaccinations delivered. Five hundred twenty-six thousand people received at least one dose in about 2.1 million doses.

As you can see, the differential here between people currently drawing paychecks -- active or reserve -- and those who have completely left our system, this archive group is beginning to grow as time has elapsed so that these bars reflect the people currently in service -- as we go.

So where we stand is that the Department of Defense is in the process of staffing -- up to Mr. Rumsfeld for a decision.

In my words, how far, how fast and how broadly to resume vaccination -- it's basically using a zero-based approach to the decision-making, and so he's being presented with five options, one of which is post-exposure vaccination only, vaccination for special-mission units and research only, which is essentially our status quo at the moment.

And then the next three are -- for those of you who knew our phasing terms, this is essentially our phase 1, vaccination of personnel going to or having returned from high-risk areas -- phase 1, or an end state of vaccination of forces most likely to deploy which would be phase 1 and phase 2 in our original plan or phase 1 and phase 2 and phase 3 vaccination of

the total force as the option's being presented to him.

As we approach resumption, we are cognizant of the need to pay very close attention to four issues, the first of which is -- results from a finding from the AVEC -- Anthrax Vaccine Expert Committee -- of people looking for the largest subcutaneous target being the area over the triceps, the vaccine causing swelling, the swelling causing pinching of perhaps the ulnar nerve, and so, as you see over here in this poster, way over here on this board -- and I have about 30 copies of this with us -- we've developed a poster on injection technique generic to all vaccines but which calls for -- as well as other documents -- going to -- administering the vaccine in the subcutaneous tissue over the deltoid region rather than over the triceps region.

We are cognizant of the need to take great efforts to avoid vaccinating women who are pregnant or who might be pregnant, so each of the surgeons general is in a process to communicate that to their health care providers in the field, the screeners, the immunization givers to make sure that we've taken adequate steps to counsel women of the need to avoid -- to defer the vaccine in the case of pregnancy and to avail the women of the opportunity to get a pregnancy test if they wish to do so.

We also are aware of the need for greater efforts at -- or attention to the precision of vaccination -- of vaccination dates entered into the immunization tracking systems,

all of the -- it was especially clear with some of the pregnancy analyses that the -- that the degree of precision of date of vaccination in relation to date of conception or date of delivery -- is extremely crucial to the -- to doing good science.

And so it's a question of putting the effort into making sure that a good job has been done.

I had promised Dr. Ostroff and others of the board that we would perform a review of each of the immunization tracking systems for human factors for the use of those data -- those software systems using default dates, defaulting to today for the date of vaccination which seems like a nice labor-saving device but bears the problem if -- if vaccinations were given last week and someone is catching up with entering the data into the electronic systems, if they don't pay attention to changing the date from today back to whenever the shot was given, it can lead to error.

And so we've done a review of each of the immunization tracking systems screen by screen; we'll be providing that feedback to the data managers, to the informatics people so that they can take that into consideration into refinements of their systems.

One of the things we've never done -- we probably will have some manner of audits -- of these precision of dates -- the details there are still being developed.

One of the things we have never used much in the

databases -- and therefore don't know how reliable the coding or the data entry has been is the medical exemption fields, so that's another thing I want to pursue as well.

And then the quality of education -- we had an unprecedented information campaign back even as early as 1998. It was not enough, and so we have gone through a process of enhancing, revising video products, PowerPoint files and multiple, multiple channels of communication.

And then one other issue that specifically relates to the board is the question of acceptance of prior doses in terms of deferral of schedule.

So what we -- from the terms perspective, the question is, do I have to start over?

And the answer is no. What we would like to say very plain and simply is every previous dose you've gotten counts, and that is consistent with previous AFEB recommendations with one exception. Back in April 1998, the board had recommended that, if there was one dose given and a gap of two years, that that dose 1 be repeated, and we are interested in whether or not the board would be willing to lift that cautionary step and simply let us count every previous dose.

This is already a six-dose series. The window of vulnerability is about two weeks between doses 1 and 2, and all of the -- all of our scientific advisors are recommending this step to us.

So I'll stop at this point and see what questions the board might have.

DR. OSTROFF: Let's take a question or two, and then you also have to give us a presentation on smallpox.

Let me turn to Dr. Winkenwerder and ask him if he has any comments. This was obviously one of the most controversial and difficult issues that we dealt with over the last couple of years, and now with the approaching resumption we'd be interested in some of your thoughts.

DR. WINKENWERDER: First of all, let me just compliment John for an outstanding summary/overview of the whole matter in bringing everyone up to date on all the work that has gone on for the past months and years on this issue.

This is indeed a tough issue from the standpoint of the variety of opinions and feelings and almost religious belief in some quarters about this vaccine.

At the end of the day, we have to make a decision -- I have had to make a decision that rests on data, rests on science, and it comes down to, is this vaccine safe, and is it effective? You know, the basic questions that FDA addresses.

And, of course, they have made their judgment in terms of licensing Bioport, and of course we have to make our judgment based on all the -- obviously that as a foundation, rockbed foundation of the policy, but then going even beyond

that, I think, to look at all of these studies, all of this information to draw some conclusions, even within DOD -- obviously having to play to a lay leadership audience, it's important to speak with facts. It's important to take the mystery out of this to the extent that it is there. It's important to take the anecdote out and to present the science and the information.

We've done that over the past couple of months in terms of vetting (ph) the various different policy options that John has described here that I had to ask people involved in the program to come up with a variety of options that we might pursue.

But we start really again to go back to "Is this safe and effective?" And we've drawn the conclusion yes, it is; yes, it offers protection, a layer of protection that we would not otherwise have.

So with that a starting point, then the question really is -- it becomes an issue of how to define those at risk and where to protect people that we believe might be most at risk, and also this time around we've got the consideration of domestic homeland security and the civilian population.

So we have been in constant communication with people at the CDC, with the FDA and with the leadership at Health and Human Services, and they are in a sense part of this -- this is not just a DOD approach; certainly it's a DOD policy, but it's

embedded in a national policy and approach, and that is to say that yes, this is a safe and effective vaccine for prevention.

We believe it's safe from the post-exposure situation.

We've got more work to do to get out of an I&D status to get to a license status for that use.

And so we're moving things along, and I think have gotten a very receptive audience among the military leadership and among the civilian leadership right up to the secretary who I know is -- knows generally about the matter, but we're literally on the issue of moving forward here.

Obviously, an important thing that we're interested in as well as -- that John referenced -- is the Institute of Medicine study, and it would be -- we certainly -- in the direction that we move, we wouldn't want to be at variance with anything that they would have to say. That would be a sort of colambitous (ph) situation if they were to have grave concerns or even, you know, significant but minor concerns.

What we are informed of at this point is -- I'm not given any reason to believe that there are going to be major concerns or even minor concerns, but we'll wait to see what -- and I haven't seen their report. They will share it with us before moving forward to share it publicly.

But -- so we've got these -- a couple of last

touch points, if you will, before we move forward, but we think that these options lay out to -- the various approaches and whatever we do, I think everyone can be assured that we're focused on trying to do the right thing, and I think we will do the right thing.

DR. OSTROFF: One question that I had asked when we --

DR. WINKENWERDER: Yeah.

DR. OSTROFF: -- were all on the phone a couple of weeks ago is the degree to which any of these policy options would be driven by vaccine availability. I don't know if you can comment on how much --

DR. WINKENWERDER: Right.

DR. OSTROFF: -- vaccine will actually be produced.

DR. WINKENWERDER: Well, let me just say this. I think that our -- in the past, we've been in the unfortunate situation of having the supply of vaccine or ability to procure the vaccine drive the policy. We'd like to be in the other position where the policy drives how much vaccine we need or want.

And that would apply for other things -- the discussion on smallpox or even the discussion we had yesterday with adenovirus. I think the goal is to have a policy that makes sense and then to create the supply and the distribution that we

need to support that.

But that said, we have to at the same time be practical. In the situation we're in right now, we will -- even though Bioport will be producing, we understand in the range of two million doses in addition to these test lots that they've produced of about a half million doses over the next 12 months and then ramping up further from there -- practically, we couldn't vaccinate the total force just because of the vaccination schedule and the time. We couldn't do that.

One of the things we don't want to do is -- in all likelihood -- is to establish a policy that we can't execute on.

And it doesn't make sense to do that, and then there are other reasons why the total force approach at this point, given the civilian stockpile concerns, also may not be the practical approach to take.

Whether that becomes an approach at some later point in time when some of the supply issues are resolved, that's another question, but we don't have to deal with that today. So that's how I would answer that question.

DR. OSTROFF: One or two questions before we move on. I don't know -- Greg or -- do you have any comments about --

DR. WINKENWERDER: I'd be interested in -- yeah, any comments that people have as well.

DR. GARDNER: I'm -- cut me off if I'm off base on

this a little, Steve. It seems to me we're dealing with a situation -- as you say, where the lay leadership is ultimately going to make a very important decision here, and clearly for a disease as we hope as going to be as rare as inhalation Anthrax, the safety issues are going to be absolutely prime, and we've gone through a rather tough few years, I think, in U.S. vaccines when the disease instance has been zip -- very low, and each event turns out to be -- the adverse event is magnified.

We -- and I guess the MMWR is recognizing this week that the -- there is a study going on now with regard to Anthrax vaccine and birth problems.

So I guess this looms very large -- and my thinking is -- it's exactly how it will be handled as we move forward right now to implementation. We should have been able to put that on the -- a little bit of a back burner, and we won't have definitive answers, still, for quite awhile, I think, as we go back and reassess the input and output of that study.

I think that is a significant issue. It will be -- if we go forward and say, "Let's go a little more," and then turn around eight months say, "Oh, there's a big problem here we didn't tell you about" or "we were still looking at," then I think we are in some trouble.

So I don't have an answer, but I'd be interested in thoughts as to that sequence.

DR. POLAND: I guess a couple of points. One, I

only wish we'd have had John Grabenstein and AVIP (ph) before we ever started talking about immunizing troops because he's just done an outstanding job in providing data and influencing in a very positive way the whole process.

Your last point, John, as all your points are, is a very important one. I wrote that recommendation, and my recollection of it was: one, we had very little data on which to make that, so I think it is appropriate to revisit it, and what data we had, I believe, related to a guinea pig model which we've subsequently learned is a very poor model for understanding.

LT. COL. GRABENSTEIN: And it was also related to the gap between 1991 and 1998 --

DR. POLAND: Correct.

LT. COL. GRABENSTEIN: -- when the Gulf War -- a seven-year gap.

DR. POLAND: So I think it would be very appropriate for us to revisit that last part, and in addition to not having data that would drive that recommendation, it profoundly influences the feasibility and the acceptability, probably, of particularly going with the total force immunization program.

DR. GARDNER: Greg, let me make one other point with regard to this from the advisory committee immunization practices.

In the general reqs, there is the statement made

that we count all previous doses, and the interval not be -- send us back to base 1.

So the idea of --

DR. POLAND: That's a good point.

DR. GARDNER: -- changing it back would make it consistent with the general recommendations of ACIP and the pediatric and --

DR. POLAND: It's a good point. I don't know of any vaccine --

DR. GARDNER: Exactly.

DR. POLAND: -- where a longer duration, in fact, doesn't enhance immunogenicity.

DR. GARDNER: Exactly. So unless we had good data to the contrary, we should go with the standard.

DR. WINKENWERDER: Other comments or questions for me? I'd be interested in just the general sentiment since I have not been a party to these earlier discussions.

DR. OSTROFF: I mean, my thoughts about this are -- I mean, there have been now so many studies that have been looking at this from a variety of different aspects and -- certainly I haven't seen -- and I know my predecessor, Mark LaForce (ph) was -- was much more dogmatic about this than I am -- about the safety of this vaccine.

The problem is, as you go forward, I think, the next-to-the-last bullet which is the issue of making this

acceptable to the troops -- and I think that that's an absolutely tremendous challenge because unfortunately it developed a terrible reputation because of a variety of different factors from the last go-round, and you know, you have to start laying the groundwork now for a policy that may be implemented in the next couple of months to get them in a mindset that's going to accept whatever policy decisions are made.

I think the only other comment I'll make is that one of the things I think we were quite pleased and somewhat surprised by was absolutely how effective the antibiotics were in the post-exposure setting.

I mean, basically -- and again it's an issue of how exposed were all these people, but it was 100 percent effective.

And that's something that we always have to keep in mind, and you know -- as we move forward -- I mean, I am not a particularly strong advocate of, you know, having deployed troops out in the field and thinking about starting a vaccine series post-exposure, and I'll just put that on the table. I just don't think that's the time to be vaccinating people, and I've never thought that's the time to be vaccinating people.

One more comment?

DR. ENGLER: Dr. Engler, and I would just like to add to John's slide about enhanced detention because there are issues for the clinician side of the equation.

You don't just have to make it acceptable to the troops. You also have to make the program acceptable to the clinicians, and there is a huge problem in that the program as it was had a one-size-fits-all rigidity that in many ways and many folks' perception interfered with the ethics of clinical care.

Vaccines are prescription drugs, and the standards of practice for adverse drug reaction management -- vaccines, just like any other drug, there is a one-to-two-percent rate of adverse event that you're not going to detect on the epidemiologic surveys; they are rare, and I think everyone in all of the eminent groups that have reviewed it acknowledge that our understanding of rare adverse events is very poor and needs to work across the board.

But those one or two percent -- a question arises about continuing the immunization schedule as is.

As an immunologist, I'm going to tell you that there is in the population hyper-responders. We've seen them. We've seen them become ill. Folks felt pressured by a policy to continue immunizing, giving oral steroids to block the side effects of someone who is undoubtedly already immune.

If we don't have attention to options to facilitating quality patient care, the program will not be acceptable, and the same furor that existed before will arise again.

We see patients who have had clear adverse events,

and they are pressured to continue to be immunized because the interpretation of the policy is that you must have exactly as the package insert where there's no other way have we practiced that way in the past. In the past, we also had options.

We have no way at the present time in the clinical front lines to measure whether someone is a hyper-responder, and to gather the data to begin to validate some of the clinical guidelines that we develop, extrapolating from other vaccine experience.

So the immunization health care component, the training at the front lines, the enhancing of VARES, I can tell you that lots of people who have had serious reactions haven't had VARES filed, and we're trying to work to increase that understanding -- also needs to be a focus because, if we aren't doing good safety surveillance for rare adverse events, the credibility of the program will suffer.

One bad outcome not handled well scares 10,000, if you will, and that needs attention, and it needs resourcing, and that's my appeal from the clinical front lines.

DR. WINKENWERDER: Let me just comment on that. Those are very good comments, very good observations, and I would agree 100 percent with everything you had to say, and as John knows, I've pushed not just on the Anthrax vaccine office but more broadly on the surgeons general and on Ms. Embrey, as she knows -- on the whole piece of communication and education, and

we have had a working group on that now for about six weeks that's been working the communication issues.

And the way I view it, being a person with a business background, is this like a reintroduction of a product that had a bad, you know -- had a bad start in the market once before, and we've got to sell this, and we've got lots of different target audiences. We've got the members themselves; we've got their families; we've got the providers; we've got the public at large; we've got Congress; we've got lots of different audiences, and they all need to be educated. And so it's a big effort.

We are engaged with the Office of Public Affairs, Tory Clark's office, on this whole issue to pull in.

One of the things -- and you can help on this, if you're so inclined -- is that we've also turned to groups of outside experts who can speak to the issue of the safety and be a sounding board. It's far better for you, frankly, or for someone from the Mayo Clinic or Hopkins or elsewhere to speak to the safety issues than it is for me.

I can say it, and I can say it with all my heart and belief and all the credibility I can muster, but at the end of the day it's going to be more effective for others to speak to that issue.

But we've got to go beyond that to the education and I believe as well the issue of flexibility -- in terms of the

program. We've got to be more flexible.

I've heard the message about -- you know, the one size fits all and this sort of mindless approach to vaccinating people in their last week of service as they're walking out the door and various different things that just don't make sense, so we've got to figure out how to communicate that and get it implemented in that fashion.

DR. OSTROFF: And I think also fighting the disinformation is also going to --

DR. WINKENWERDER: We have to do that. Yeah. Ellen?

MS. EMBREY: This is Ellen Embrey. I also wanted to comment that Dr. Engler is in Walter Reed, heading up the Vaccine Health Center which was specifically mandated that we form a capability to deal with adverse effects and to network through that, expand our capability to provide support, and I've asked her, based on similar comments that she gave to me directly, in preparing for our follow-on, to come up with a proposal on how we would educate those providers as we begin to resume our vaccination program, specifically how we can expand her expertise through our network.

And I hope she's working on that.

DR. OSTROFF: We're going to have to move on, Renata.

DR. ENGLER: Okay. I just want to make comment

that education also requires some clarity about the flexibility piece, and so either -- we're working on it but we're also waiting for certain decisions and certain issues that we have particular concerns about and that I've spoken to John about.

DR. OSTROFF: Okay. Well, let me just say on the part of the board that we're committed to helping you work through this policy, and we'll do whatever we can to help you come up with a policy that makes sense and that's acceptable, and we'll continue to do so.

Let's have John move on to the smallpox presentation, the other difficult issue.

LT. COL. GRABENSTEIN: Anthrax is child's play. Let's talk about smallpox.

Smallpox -- I will breeze through the slides to get to the comments. Smallpox would be devastating as a -- if released from a military -- from the health of the troops themselves, the outbreak could restrict movements of troops, aircraft, ships, divert manpower and stress medical operations to a tremendous extent.

A history primer -- Canada may be a separate country today because of smallpox -- if it had not been for smallpox, we might have won the Battle of Quebec.

(Laughter.)

LT. COL. GRABENSTEIN: So congratulations.

(Laughter.)

LT. COL. GRABENSTEIN: There's also a very interesting 100-page diatribe from an enraged citizen to Woodrow Wilson in 1919 in the UMC Health Sciences Library about how terrible the smallpox vaccination is.

This is a timeline we found useful to try to get synchronized -- you know, when you were born, what your current age is, and with some assumptions when you might have come into the service.

Smallpox vaccination became intermittent in '84 and basically stopped in '89 or '90, so therefore the years since your last vaccination, what fraction of the troops that is -- and the good news is that those of who were vaccinated -- let's see, I was vaccinated about -- my last vaccination was roughly here, so my odds of death from smallpox is far less than 30 but far greater than zero.

We consider that we have a special duty to protect three-point-something million people in terms of DOD's responsibility to protect against smallpox.

The military personnel, we usually think about, but because of the contagion, we've been taking into account family members and our DOD workers who are overseas, and there's almost a quarter million of them, and family members residing on base U.S., about 600,000 of them.

If there's an outbreak in Fayetteville, North Carolina, who's going to take care of the troops living on Fort

Bragg, the troops living on Pope Air Force Base -- that sort of thing.

So where would we find 3.25 million doses? Well, if we can assume the dilution studies, which we're waiting for the results of, we would only ask to maybe borrow 625,000 doses of DRYVAX from the CDC, but, you know, it would be basically -- you know, this is one way to do it if time constraints fell.

What we would like is 12 million doses of our own vaccine, and the number, 12 million, is my creation by taking in the calculation of anybody for whom we have any kind of responsibility -- any kind of ID card holder, whether a troop or civilian worker or what have you.

Right now, the requirement is 300,000 doses and there needs to be a verb in this line, and the verb is "need" -- the joint vaccine acquisition program needs 10 million dollars to get on with its phase 1 and 2 trials and to increase the lot sizes, and it has not yet received that much.

I've also provided at the front table -- and I've got a few more copies here -- a description of each of the various smallpox vaccines and each of the various vaccinia immunoglobulin products.

The original intramuscular form has turned pink from some leeching from the vial stopper. There are about 500 treatments, and if you assume one treatment per 10,000 vaccines,

that's about enough for five million vaccinations.

We want to create an intravenous form, one lot of which could be used in an emergency, has a bit too much moisture left over from its manufacturing process -- that's about another 350 treatments.

Joint vaccine acquisition program needs five million dollars to process some frozen plasma into about 5,000 more treatments under subcontracts to the Massachusetts Biological Laboratories.

And the supply shortage basically restricts us to managing vaccine complications as opposed to an older policy of using the vaccinia immunoglobulin in combination with the vaccine in immunodeficient people which there are far many-er (sic) of than there used to be.

And that supply is the nation's supply, even though it's in DOD hands, which is not good.

But I understand that the CDC may be having a request for proposal for purchasing some -- or manufacturing some VIG of its own.

So what have we been doing lately? I think Major Balough commented yesterday there's a contingency I&D for full-strength DRYVAX that's in development; it's in staff -- it's past the IRB process; it's in staffing, and hopefully we will get it submitted to the FDA in short order.

There are other I&D's further back in the pipeline

for VIG and for sodovovir (ph) both for vaccinia vaccination reactions and for variola cases.

We are grateful to the CDC that they've invited -- or given us several seats at a 13-to-15-March training conference on smallpox.

We've developed a variety of brochures, lay language cards, what have you, both from the Army Center for Health Promotion Preventive Medicine and our own agency, and if anybody else has been working on them, we'd like to collect a complete collection, so I'll trade you copies of ours if you'll give us copies of yours.

We also are working on -- for a variety of these contingencies I&D's -- using technology like you use at Best Buy to allow us to use electronic signature capture for I&D's to reduce some of the paperwork burden.

These websites are not live yet, but we are envisioning content for them and working in that direction and working on a much more sophisticated concept of operations and specific plans.

So if there were an outbreak tomorrow, what would we do? We started working with the joint preventive medicine policy working group to develop plans for response teams, epidemiologic response teams -- well, USAM is working on a sodovovir team, and I&D implementation team -- we intend to plagiarize as much as we can from what CDC has already done for

its domestic policies and -- and build on that for our global responsibilities.

We have not yet, but we intend to ask CDC for a very small number of doses to vaccinate response teams and then operate the -- offer the vaccine under I&D consistent with what CDC is doing.

Well, what if there is no outbreak? What if we have the luxury of time?

We would like to consider the issue of prepositioning some vaccine and some VIG outside the United States. You can imagine that, if there's a smallpox case anywhere, international airline travel is going to come to an abrupt halt.

We need to get that DOD vaccine requirement raised substantially, accelerate the production of the vaccine and the VIG.

We are struggling, as I think CDC is struggling, to figure out what the right thing to do is -- how far to go down the road of known side effects when there may not -- when there may be a great benefit or no benefit at all, and not knowing whether the benefit is going to be great or zero.

And we are confronting the process of evaluating the risks and the benefits of resuming universal smallpox vaccination of military personnel. We are -- let me say that again. We are starting to think about it -- is the best way to

phrase that.

And one way to do it would be to simply wait for FDA licensure of a cell culture-derived vaccine. That's quite a number of years away, and it's basically a threat assessment to determine whether there is some overwhelming need that would drive that to be needed sooner.

So some rhetorical questions at this point that -- you all might have your own, but these are some of the ones I have -- how special are we? Should we just hold ourselves to the same standard as the civilian populace?

If the CDC says, "Don't vaccinate civilian health care workers," does that automatically apply to DOD health care workers, or should we vaccinate ours anyway or whatever?

The contagiousness of this is very different.

How aggressively should we pursue pre-outbreak vaccination? How completely should we -- I mean, we could shut down -- we could vaccinate these people and, you know, lock them up on bases for 21 or 28 days, but how much liberty might we take in not going to such draconian measures, and what have I failed to consider?

This is the -- I'm working up a very intricate planning matrix of all the documents we need to create eventually which we will whittle away at, but these are some of the domains that we're considering -- threats, operations, supply being very critical to all this -- regulatory from the standpoint of the

I&D's.

Are there conditions under which it would be appropriate to waive consent because of the community responsibility, characteristics of an infectious disease rather than a -- or a contagious disease rather than a noncontagious disease?

You know, what are our responsibilities with regard to our allies and civilian policies?

And waiving consent is not a simple thing, so I've broken it up into at least four different scenarios -- before and after outbreak, CONUS overseas with people traveling or not traveling -- very complicated issues in clinical care both in how do you scarrify, who do you exempt from pre-outbreak vaccination, how do you manage adverse events, how much do you isolate, worker safety with those wacky needles.

And then for variola cases, if, God forbid, we should have some, what's the rate -- how do we move them? Where will we put them? What decon? How much isolation? What are their special needs in terms of pain management, the laboratory in sampling and whatnot -- education, education, education.

If we vaccinate, who first and where first? If we want more VIG, we need more donors for plasma, and how do we respond to an outbreak?

So it's that simple.

(Laughter.)

DR. OSTROFF: This one, you can do in your spare time.

Let me open the discussion about this because it's a -- you know, this is a very difficult issue, and I think that the board is going to get tasked with addressing some of these questions in the not-too-distant future.

But in DOD -- and I'm sorry, I had to step out for a minute, so I didn't see all of your presentation. I mean, you vaccinated until 1990, and so all of these questions that you're raising about the administration of the vaccine -- how did they do it then? Because at that time, they were the only ones vaccinating.

LT. COL. GRABENSTEIN: Well, the bulk of the vaccinations delivered were at basic training sites where there was a built-in isolation factor.

Now, I got two doses -- I got a dose going into ROTC camp in '78, and then I got a dose at Walter Reed in '83 or so -- haven't had any since.

The one -- I don't remember getting any particular wound -- you know -- the wound management, the vaccination site management instructions I got back then were -- I don't remember them -- whether I got any or not, but we're in a different era.

DR. HERBOLD: One of the issues is --

DR. OSTROFF: You need to just --

DR. HERBOLD: Oh -- John Herbold. The cohort

effect -- I'm reflecting back -- it was in '84 when we had the recruit who was vaccinated and developed disseminated vaccinia and -- which was one of the stimuli for total force testing for HIV because this person was HIV-positive.

I think back on my middle son who was born in '72 and we had to ask the pediatrician to vaccinate him, but my wife had been vaccinated, so the colleagues of the folks who were being vaccinated in the '70s -- the parents, the siblings, the girlfriends -- all had been vaccinated at birth.

And so it wasn't until we got into the '80s, when we had a large cohort of people who were born post 1970 who then provided this pool of unvaccinated individuals -- wives, siblings -- that -- then the risk for contact.

And the other piece of this is that mid '80s the vaccination at recruit training of -- for -- with vaccinia varied considerably between the services. It was not 100 percent. I think the Air Force stopped somewhere in the mid '80s and just chose to never start up again.

DR. GARDNER: I wanted to also follow up on one of the --

DR. OSTROFF: Pierce Gardner.

DR. GARDNER: Sorry -- Pierce Gardner -- the change, obviously, when we stopped vaccinating the general population and now -- we used to worry about people with unrecognized psoriasis and eczema. Now we've got a survey to

worry about -- not only the individuals themselves but the individuals who live with individuals who might be HIV-positive.

So what kind of -- that seems to complicate things quite a lot.

LT. COL. GRABENSTEIN: Yes. Certainly, the issues of how much childhood -- what degree of childhood eczema contraindicates a pre-outbreak dose. You know, an adult -- there's going to be a lot of reasoned -- a lot of reasoning from -- not a lot of evidence but a lot of reasoning to try to figure out what the right compromise is between safety and practicality -- you know, perfect safety and practicality.

DR. OSTROFF: I mean, this is a difficult issue, you know, in terms of the active duty population. I can't think of a potentially safer population in which to use this particular vaccine, but if you're starting to talk about dependents and if you're starting to talk about civilians, you get into all of these very, very difficult issues which we're grappling with in terms of what we would do with using this particular vaccine -- if we had to do so on a large-scale basis -- were never issues when we previously used it in a civilian population.

But, you know, I'm of the personal perspective -- and I'll say this quite frankly -- if the intelligent assessment is that the threat is there, then I think some of these options have to be very seriously considered, and that is because these are the people that are going to be

overseas, and these are the people who are -- you know, it's one thing to bring it here and release it here. It's another thing to do it where it may be present, and they'll be the vectors, and that's part of the reason to consider them sort of as a special group.

DR. GARDNER: And I guess sodovovir looks reasonably okay in preliminary studies, but that would at least give you a way to manage the complications better than we used to have --

LT. COL. GRABENSTEIN: Yeah, I've not -- I can't quote the effectiveness evidence by heart, but it is a very -- it's intravenous with predose probenecid; it is not an outpatient procedure -- you know, obviously.

DR. OSTROFF: Yes?

DR. ENGLER: I just want to caution that the medical exemption challenge -- there's an actually increasing incidence of atopic dermatitis in the population, and the dermatology community is very concerned because we have a lot of people who have mild to moderate atopic dermatitis on topical steroids who continue to serve.

We also have a fair number of people who are survivors of cancer, chemotherapy, the concept that, you know, all of active duty is perfectly healthy and doesn't present real, huge challenges for screening, and then how do you manage those exemptions -- it's not minor.

And the other issue is the risk to the family members at home and the contact potentially for pregnant and immunocompromised individuals who are virginal in terms of any immunity.

And we have -- still had been giving smallpox at Walter Reed because of the laboratory workers and stuff and -- so we have some experience in, you know, protecting the deliverer -- how we would -- a fairly poorly trained infrastructure -- I think it presents huge implementation challenges and resource requirements to do correctly that I think need to be considered in any policy that might be implemented.

One positive thing is that about -- an awful lot of us do have a history of both -- of two doses, and just in a survey this late fall at Walter Reed of the employees, 35 percent of them had memory of two doses of smallpox.

So we have a fairly large population where booster dosing and perhaps saving vaccine at a 1-to-10 dilution 'cause they are booster within DOD might be another consideration and a project to consider.

DR. OSTROFF: There's a lot of issues here. I didn't say it was a safe vaccine in an active-duty population. I said it was probably the safest group of individuals in which you could give this vaccine, but that's not quite the same as saying that it's safe in that population.

We're going to have to move on in a second. I

have one question coming back to Anthrax, and I was a little concerned about something you said in the presentation regarding pregnancy screening, and I'm wondering if the preventive medicine officers could comment on how they're implementing Dr. Winkenwerder's -- and the surgeons general's decrees to strengthen that screening, and I guess the question revolves around giving women the option of receiving a pregnancy test versus making it a requirement.

CAPT. YUND: Jeff Yund from the Navy. Our guidance is still in draft, but we're taking caution not to -- not to rely too heavily on a negative pregnancy test.

I think that -- I think that, if a woman desires a pregnancy test in a situation like this, it's probably an indication that she's at greater risk for being pregnant than a woman who doesn't feel that she needs a pregnancy test, and the Navy is going to take pains not to let either the woman or the providers rely on a negative pregnancy test and to conclude that there's no chance that the woman is pregnant because obviously very early pregnancies will be missed.

COL. GUNZENHAUSER: Jeff Gunzenhauser from the Army. I think, if I understood your question correctly, it was whether we would allow the woman to make the decision whether or not there's a need for a test rather than medically recommending that we really think it's indicated, appropriate in certain folks, and our policy really includes both of those.

We put out policy, and there's quite a bit of discussion about what its intent is.

As I understand it, the final part about asking whether or not the woman would like a test is a final option after the medical assessment has been done, certain questions asked. A test may be recommended at that point.

But then at the end the woman may still have the option to request the pregnancy test if she would like one.

LT. COL. WOODWARD: Kelly Woodward from the Air Force. Our policy is also -- our guidance is also in draft.

Our approach is really to follow the ACIP recommendations which are very -- that were actually reinforced at MMWR last week, and that is all people being vaccinated be -- have administered a screening questionnaire that we are going to be proposing -- the CDC's published questionnaire for adults and children -- be the screening questionnaire which includes questions about pregnancy.

And then this is a little bit complicated because we don't want to send a message that, if one's pregnant, one should not receive any vaccinations because there are some that pregnancy is an indication to be vaccinated -- such as influenza.

So we're wanting to use the screening questionnaire, and then, if there is any question about a woman's answer, it's the provider who ultimately makes the determination of whether she's pregnant before administering any pharmaceutical

agent, and we want to make sure that that's a process that's already in place in our clinics.

If someone thinks they're pregnant, before they get a drug that's contraindicated in pregnancy, the provider makes that determination as to their pregnancy status before the drug's administered.

And we are then linking that with -- trying to get some sort of documentation of this in our automated immunization tracking system so that we know either that the questionnaire was administered and responded to or we're debating whether specifically to have in there that the woman answered negative to a question about the possibility of being pregnant.

That's a little tougher because, again, it gets into the issue of which vaccination you're giving. Some of them, a positive response to the question of "Are you pregnant?" isn't a contraindication to giving the vaccine.

DR. OSTROFF: Dr. Ness, do you have any comments about this issue or --

DR. NESS: Well, I guess I'm a little concerned to hear that the implementation of the policy appears to be -- or the recommendation appears to be fairly variable from service to service.

On the conference calls that we had regarding this issue, the recommendation I made was that a woman be asked whether she had an absolutely normal last menstrual period in

which case there's actually data to suggest that those women are unlikely to be pregnant. It's conceivable that they're pregnant -- you know, very, very early in pregnancy, but it's unlikely.

Many women, when you ask them the simple question, "Do you think you're pregnant?" will say "no", but indeed they had an abnormal last menstrual period which indicates that in fact they do have an early implantation.

So my recommendation had been that you ask that simple screening question and that indeed for anyone who answers that they had an abnormal last menstrual period or they had no last menstrual period, that all of them be certainly offered pregnancy testing and indeed be encouraged to be tested.

DR. OSTROFF: Thanks.

DR. ENGLER: I just want to speak to -- Dr. Engler -- in regards (sic) to the OB/GYN military experience.

An awful lot of active-duty women who engage in extreme activity, if you do surveys -- they have a far higher percentage who don't have regular periods, so that that experience in certain populations may not extrapolate to the military women's population -- particularly deployment settings, high training settings -- just like athletes. Menstrual periods tend to become more difficult to interpret.

And I personally can tell you, when I was still out doing GMO work, women coming in in delivery and not knowing

they're pregnant and having had irregular periods for a long time.

DR. NESS: Again, Roberta Ness. My answer to that would be great. Overtest.

DR. OSTROFF: Thanks. We're going to have to move on. Colonel Grabenstein, hats off, and we'll look forward to hearing --

LT. COL. GRABENSTEIN: I'll be back.

DR. OSTROFF: We're going to go back to the recruit assessment programs, and I think the next presenter is Colonel Wells on the -- from CHPPM.

COL. WELLS: Thank you. It's good to be here today. I'd like to take a moment to plug our upcoming eighth annual recruit and trainee health care symposium at another beautiful coastal city -- Baltimore -- 15th to 18th of April, 2002.

Our focus will be a little different this year. We're moving slightly away from the basic training milieu and talking more about more advanced levels of training such as Army special forces training, Army Ranger training, and we hope it will be more interesting for the audience at that time.

The Army Recruit Assessment Program is a little more than notional but certainly not as far along as the Navy at MCRD and Great Lakes Naval Training Center.

How we got started was that Craig Hyams came

bearing gifts, and he asked if we would be interested in starting up his Recruit Assessment Program at one of our Army sites.

And it is of great interest to us at the Center for Health Promotion and Preventive Medicine to get this kind of surveillance data for other people to use to understand our force better.

So we selected Fort Jackson, South Carolina.

Now, when we say "we selected," we went through the entire process of talking to our then-deputy chief of staff of personnel, Lieutenant General Maude who was killed in the September 11th bombing, got his approval, got the Sergeant Major of the Army approval -- Sergeant Major Jack Tilley, and the deputy commanding general for individual entry training for our training and doctrine command, General Van Alstein.

They were all concerned, particularly General Maude and Sergeant Major Tilley, that we not use this tool to screen out anybody from service but to understand who they are better.

Well, the reason we picked Fort Jackson and got approval to go there was that it is our largest training center, training about 34,000 recruits a year, and it trains far more than three quarters of all our women that come in, at about 15,000 per year.

Their command, dating back before Brigadier General Bester and when General Van Alstein was commander at the

base there -- have had a long interest -- longstanding interest in prevention activities, primarily in the injury spectrum, but they're interested in all things prevention.

And so we've had a long-term relationship with folks down there, and it was a natural fit.

While our survey instrument is the same as MCRD's, we've worked over the last few months to make changes with NHRC's instrument; however, we do have the female questions. There are 17 of them, adding up to a total of about 130 questions.

We began process-testing of the questionnaire in November. We did a test/retest on 100 men and 101 women and then did a large group test just to test our logistics to see if we could get in a large number of soldiers into one space and get them through a survey in a reasonable amount of time.

The survey took about 20 to 30 minutes for both groups.

During the test/retest, men and women were divided in a large room, about this size, with a divider that went down the center.

They're sort of in study carrels, so it's not easy to see what the person next to you is writing as answers.

So we thought that was -- we were able to do it pretty successfully. We had the support of the reception battalion command.

However, we don't have interest from our

operational folks at Fort Jackson in speeding along the CHCS registration process. They just don't want us to interfere too much with their in-processing.

So, while our medical people are interested in this CHCS in-processing, the operational people aren't, and so that's where we were at before the Christmas break and when all the soldiers went home in something called Exodus.

We were planning to begin operational implementation of the survey after Christmas, but during the Christmas break questions arose about this being research versus not research, and currently we are planning to add on to the NRHC protocol with NHRC as our executive agent.

Our second-level IRB will be at the CIRO office at Fort Sam Houston, and we hope to start up again in the first of May this year, reenergizing the operational folks at Fort Jackson to start up something again that has been stopped for awhile. It's going to be difficult, but we still have the support of the higher levels in command.

Our budget was relatively small -- 100,000 for our startup and first year. We'd like to increase to one and a half FTE's as NHRC has done at MCRD.

And that's my presentation for now. I'll be followed by Lieutenant Kaforski from Great Lakes Naval Training Center.

DR. OSTROFF: Thanks. Why don't we try to move

through a couple of these, and then we'll come back to questions.

LT. KAFORSKI: Good morning. I was very excited to be able to come and talk in a forum where we can give our opinions across DOD on this issue. I think in the big picture we need to understand that there's not a lot in common -- among recruit training centers, there's not really a lot in common with the rest of the medical system.

We have more in common with each other, it seems, than we do with our own medical systems. We're kind of isolated out there. We're not operational, and we're not a medical facility.

So it's good to get together because we have a lot in common, and we can solve a lot through these common issues.

As has been mentioned, Great Lakes has been doing a lot as far as innovation with the recruit in-processing, using technology to do that, and they -- we have been administering a questionnaire since 1995. We're still administering that same questionnaire.

That basically came out of necessity, and around 1995 they closed the other two boot camps for the Navy, and all training is now consolidated at Great Lakes, and we are currently processing about 55,000 recruits a year there, most of them kind of over the summer months -- it's more concentrated then.

Just in -- I've been working on these recruit issues for about four years now, and just in communicating with

the other services, I am confident -- we do have the most comprehensive medical in-processing, but that's a product of a lot of work back in the mid '90s and a lot of cooperation at the Navy site.

It seems like we get a lot more time to do the things that we need to do, and they plan that into our schedule.

So it's not necessarily by anything we've done but that we've had good partnership with the line community.

The SHIP questionnaire is 193 questions. Basically, a majority of this questionnaire is from the SF-88 in '93 -- those same questions that Captain Hyams had answered when he first came into the service.

But it gave us -- at the time, it was made for an operational necessity. It was made so that forms could be printed out more easily and just the automation of the in-processing was done.

So a lot of those questions were done just to fill in forms, things like that, but it's also nice -- again, not a research program. We get this information in a routine manner, and we use it on the operational side. We have a whole bunch of extra -- we have a whole bunch of health information that we can refer back to if we have to.

We use the input for other systems. We had a -- some several issues with the smart cards at Great Lakes

also, and we take the information that we get -- we do do some screening with it. We pull out folks with allergies and medical conditions, and we recheck those allergies and medical conditions to see if they can continue to be medically in-processed.

We do catch some folks that do have to leave the service. We've had extensive conversations with the MEPS folks about exactly how extensive they feel that their physical examination process is, and we've consistently been told that it's more of a screening.

So we are finding people that it is not worth sending those folks out to the fleet because they'd be more -- they'd be more of a problem for the fleet in the future if they continued on and went into those positions.

I think some of that has to do with the isolated -- the more isolated nature of naval operations. We're out there; they're on their own; they're out there with a single -- sometimes just independent duty corpsmen.

So we do watch that, and we do use it for screening and for -- sometimes having to let people go.

SHIP is also a bubble-sheet, paper-based questionnaire, and the RAP questions were based -- SHIP was one of the documents that was used to develop the original RAP.

Our basic function in the beginning of RAP was to go ahead and test the technology that was proposed. We looked at hardware, software, database connectivity, integration and also

again the operational issues.

Hardware is basically off-the-shelf stuff. The scanners that we're using are pretty much off the shelf. They're not cheap.

The technology is not huge. It's more the reliability of the mechanical processes of moving paper through a machine that ends up being really the big issue -- not how clear the scanning is, but can you put a thousand sheets of paper in this thing and have it read each one of those accurately and without getting jammed, just like we all experience with paper copiers.

We went ahead and used high-speed connectors which allow those -- basically you're getting images from the scanning documents, and they have to go between the scanner and the machine, so you use a high-speed connector.

The software that we've been using is a packaged software, off the shelf, called Cardiff Teleform Elite, version 7. It has design recognition and verification modules which allow you to basically -- you can make your questionnaires up in just about any format that you want to. It's very easy to change them.

The recognition part is taking the scanned document and being able to pull the answers off of it, and the verification process is basically -- it lets you look -- one of the problems that happens a lot is someone will change their

answer or it won't be clear. Well, the verification process in this software allows you to actually look at an image of that person's answer and make determinations on questions that maybe you can't really tell right off the bat what they answered.

But when you look at it, you could see that one was erased partially, and one was fine, so it gives you a chance to say, "Oh, this is what they meant," and you can go on with the process.

We're operating over Windows NT, that basic thing in the Navy, and we're using database -- very common databases -- Access and SQL Server.

I don't want this to be a big tech'y thing, but I wanted to make sure this was in the background for everyone.

Database connectivity went well. The information gets plopped straight into a database where you can do a lot of things with it from that point on. You can create reports; you can move it around; you can move it into other databases. So, overall, that was no problem.

Common systems integration -- any of these systems should be able to be used, and it's already been proven now that they're able to be implemented anywhere across the DOD, using common equipment.

Operational issues for us at Great Lakes was that it was similar to the SHIP process.

When Dr. Hyams came to us, also bearing gifts, we

saw an opportunity to get integrated. Again, it is such a huge issue, we felt at Great Lakes we were doing a lot of innovative things -- like I said, with smart card and having the SHIP already, but we had innovated ourselves into isolation, and I think that happens a lot at a lot of the recruit centers -- is every innovation that you do -- sometimes you do these things that take care of yourself, but then that data goes nowhere else; nobody else can use it; you can't send it out of your center; it's not usable by the fleet, so you end up in isolation.

So it was very important to us to say that, "Look, this is going to be tested across DOD; we can all use it. We can all start with some common core, and at least we can take, again, those common issues among recruit centers and move forward into something based on our commonalities."

So SHIP -- the process that we tested actually took longer than SHIP takes us now, so we did -- we are continuing to use SHIP basically because of the manhours required, and it -- the Teleform does require fairly extensive training, especially on those mechanical issues.

Our analysis is that the technology is viable; it could be used across DOD.

We didn't feel it was suited to very long questionnaires and just basically because you're dealing with a lot of pieces of paper, and for us there was not a real return compared to SHIP as far as changing to this technology.

Now, as far as the questionnaire and the question sets, it's very easy for us to adopt it because it's very similar to SHIP, and it's very easy to move forward once we get some sort of nod that says we're going to work together on this -- we'll be happy to go. So we're eager to share that baseline.

Critical issues in training -- and I think everyone knows that that's in recruit training -- is that we can't take any more time away from training.

We need the flexibility to allow collection of local or service-specific information. This should not be a stovepipe, stand-alone, some kind of programmed-out thing that can't be changed unless you go through a vendor.

We need to have some local abilities to be flexible, and we want to make sure there's the best technology.

When we started SHIP in '95, technology wasn't as advanced as it is today. There's so much that can be done now through web pages and things like that that couldn't be done back then.

We're doing an initiative at Great Lakes using a palm pilot for input now instead of paper. We've had a lot of history with paper, and we'd like to get away from it.

It doesn't mean it's right for everybody, but for our setting it seems to be the better thing.

And we get rid of paper; we get rid of some of the time that it takes to do it. We lose some of the flexibility

with being able to fill out a paper sheet just about anywhere, like we saw some of those pictures with the Marines.

But we expect local implementation sometime this year -- strictly on the amount of money actually getting rid of paper -- it's cheaper to go to something electronic.

Our conclusions at Great Lakes are that the questionnaire content is acceptable, and we definitely embrace it.

We don't want to continue with paper technology, but we don't think that that's an issue to stand in the way of anybody else.

Isolated application would adversely affect the acceptability for us. We need the flexibility locally.

And we recommend that RAP be a set of data requirements to report to some central place and not, you know, something that comes in a box.

So how do -- you know, you can ask your questions and get them recorded any way you want, but we think that basically it should be a set of requirements and not some huge project to feed another vendor.

Are there any questions about what we do at Great Lakes?

DR. OSTROFF: Questions? Yeah.

DR. BERG: Bill Berg. I'm curious why -- one of the themes that we've had from RAP is that it's fast -- five

minutes or so, and you're reporting significantly greater times. Is there an explanation for that?

LT. KAFORSKI: Well, the actual conducting of the tests, sir, does not take that long. It's a half hour to 45 minutes to fill out the questionnaire, but then you have to walk away with that stack of paper and run it through the machines and deal with the data quality issues.

That's where the significant process time comes in.

Now, no one -- we've had -- as was mentioned, we've had that CHCS mini-registration ability for years now, so going to RAP did not really improve anything for us on that -- on that issue.

All the other services -- or many of the other services are experiencing a lot more speed in getting processing going simply because of that feature.

DR. OSTROFF: My only comment would be that reportable diseases are required as well, and just making it a reporting requirement somewhere else isn't going to necessarily mean it's going to get reported.

LT. KAFORSKI: I guess maybe I can clarify, sir, that what I would say is that there should be a core set of questions to give at the recruit centers and then the ability for the services to add local things to it.

That's more my point is -- if we can come up with

50 to 100 questions that we know we're all going to ask, that will be a great database.

But the Navy and -- each service is going to need some separate information to take care of operational things and their own specific issues.

DR. OSTROFF: Two quick ones here. Greg and then Dr. Cattani.

DR. GRAY: Greg Gray. Lieutenant Kaforski, I appreciate your suggestion for additional innovation using the palm pilots, but your theme -- at least one of your themes was you don't want to be in isolation.

Epidemiologically, if you use a different inputting device, you may be different and isolating yourself. I mean, you might want to consider that as well in the equation.

LT. KAFORSKI: We have to consider -- we have two -- you know, on the medical side, we all want to do everything that's as perfect as possible, but the operational realities come into play.

We see 500 people in a day. It's just a huge burden, and there's so many more uses for the data, and by saving time doing things electronically, it leaves us a lot more time actually to spend one-on-one time with a recruit, verifying their information face to face.

Unfortunately, with the paper, the other thing is, once you get their answers recorded, they're gone.

Electronically, you can see the things in front of you right there and verify their responses.

Again, I don't think it's necessarily right for everyone, but we've got to reach some commonality, and we think it's in the dataset rather than --

DR. OSTROFF: Last comment.

DR. CATTANI: Jacqui Cattani. You mentioned -- and -- when we toured the Marine recruitment facility, one of the comments was a recruit's not answering correctly to some of the questions asked about allergies, for example, and on the basis of that they've later been de-selected or whatever term you use for not inducting them.

I guess my question and my concern would be that some of the highly sensitive questions on this -- for example, the one that struck me in a previous presentation was: Have you ever driven a car and had alcohol at the same time? And I was quite surprised that 80 percent said, "No, I have never done this."

Now, it would worry me a bit that the highly sensitive questions may not be answered in an interpretable fashion because they're afraid that this may be used to select them out.

Now, the -- I suppose there are two ways around that. One would be to either take out some of those questions and modify them, or the other, if you really want answers to

those questions for some specific reason would be to ask that set of questions after the recruitment is finished and they've been inducted.

I understand the importance of getting the medical data just as they begin their military careers, but some of that data you might get more honest answers that you could interpret if they didn't have to worry that their responses would be used to select them out.

LT. KAFORSKI: I think that's certainly a good possibility.

Most of the issues that we're talking about when we talk about de-selecting are things -- they go through a moment of truth and, basically, just before they come and see us, they're told how important honor, courage and commitment are and how important it is to be honest.

Well, a lot of the things that these folks may have been coached not to reveal or that they have held back somewhere through the process at MEPS come out after that -- that coaching to be more honest.

The extreme -- I will tell you -- is someone that came in with one eye -- a glass eye and a regular eye -- that passed their test.

(Laughter.)

LT. KAFORSKI: That is the extreme. And then, you know, there's just others that have been pressured into saying,

"Just don't answer 'yes' on anything," that kind of stuff.

Psychological stuff -- that is not so much a factor. It's usually the straight-up medical history things -- long-removed missing eye, things like that that actually do come out in the process.

DR. CATTANI: But I would ask -- how do you know about the psychological stuff? In other words, how can you validate the answers to those questions that -- and in fact 80 percent of these recruits have never driven a car while under the influence of alcohol?

LT. KAFORSKI: That's just going to have to be a separate thing. I mean, even on the psychological side for us, that data is only used by our psych folks to look at group information. We don't use that at all as far as screening or referral right at the beginning.

DR. OSTROFF: Do you want to respond to that real quickly?

MR. FRIEDL: Yeah.

DR. OSTROFF: And then we're going to have to move on.

MR. FRIEDL: I just wanted to say very quickly that I think this will always be an issue as it relates particularly to psychosocial data in our setting where -- I mean, even if it ultimately doesn't have occupational implications, the perception may be there that it could, and so they're going to

under-report.

And I think the uses for it -- we just have to keep in mind that the uses are as population indicators, or we also have to come up with empirical models.

The question is not -- the question is not always going to be: Is this measuring exactly correct? The question will be: People at baseline who respond in this way -- what does their future medical history look like? You know, how well can we understand their future medical history? Apart from what's actually happening at time zero and consider it as a behavioral response to a question, and what does that behavioral response predict medically?

This is always going to be an issue in our setting.

DR. OSTROFF: Okay. We're going to have to move on. Thank you, Lieutenant.

The next presentation is the Air Force -- Colonel McKnight.

LT. COL. McKNIGHT: Good morning, ladies and gentlemen. I know it's a long morning. I will be brief so we'll have an opportunity for questions and answers.

I came to my current job last fall, and I want to publicly thank very much Meg Ryan and Dr. Hyams for all the work they've done with the RAP initiative because it's traveled many times because of their efforts, and I think that I know that more

than anyone because I'm new to the scene.

These slides were put together without really seeing the presentations you've seen this morning, so you've already seen this part.

And this slide, you've also seen as well, but they really want to highlight for you today where the Air Force is coming from and that is -- we are very much in agreement with and going in the same direction and have the same purpose as those who said, "Go forward" and those who've come up with purposes.

So please understand what I'm about to share with you has exactly the same endpoint in mind.

However, our problem is -- as I climb back into the sandbox of the Air Force -- is what are the rules of engagement that I have to deal with, and I work with the experts within the Air Force from the academy, from Washington, from Brooks Air Force Base, and the thing that ultimately drove us and is -- I'm not saying it's not driving the others, but it's driving us -- is the outcome issue, the clinical care issue as well as the programmatic action -- the ability to take information and turn it into action that will ultimately improve the health of, number one, the individual who gave us the information, number two, the population that they're a part of.

So there are really four core principles that we've said we must not deviate from.

The first one, as you can see, there's the

operational value. They are our customer. We are here to serve them as the medical corps, and we keep them in our sights at all times and try to meet and understand their needs.

The second issue is the automated issue. For us, we want to start out going with an automated format period because that's medical electronic records -- everything that we're doing now is in that venue, and so what I'm about to share with you has to be from an automated format, rather than paper.

The third is personal identification. One of the things we've done in the Air Force now for six years is my talk about the HEAR -- is try to give back to the individual a way that they can improve their health because they gave us information.

And so that was one of the most basic premises that we've gone on is you've provided us with something about you; what can we give back to you to help you improve your health if you choose?

And then the link with the future that we feel very strongly that we have to have a product or we have to have a program so our RAP -- our recruit assessment tool is one where we see it linking from day one all the way through the life cycle of the airman or the airwoman so that we're not trying to further develop something down the road that we're in fact locking hands right away.

This is something you've heard the words about --

you're going to hear a little bit more about it because, like I said, I had to climb back into the sandbox where I live and talk to the experts who know far more than I do about this as well as take the input in the direction that the other sister services are going.

And so I'm going to talk about the HEAR 3.0 with the training module.

When we talk about the HEAR, it's a process that's been in evolution for over six years now, starting with Region 6.

Our customers have said, "We want to improve the health of those that we're not responsible for in an HMO setting."

And if you look at the product, it has not been a stagnant issue. We didn't have the first model first time out the gate, that in fact, as time has passed, we've been trying to make it a better -- broader, greater depth, more appropriate to what our population's about, which is what I'm going to talk about -- about the HEAR 3.

But what I want you to understand about it is that it's not an Air Force model. It's not something where we simply said, "Here, we're going to do this." We've actually engaged our sister services.

I've been told the HEAR expert is a lieutenant colonel who's in this room right now. He happens to be in the Army. We've had civilian input to kind of guide us in terms of

the domains or the topics that would go into the questionnaire.

So our goal has been to expand the expertise, get as much in as we could and take it back and create a model that would work for our population.

And so, in effect, what we're looking at is something that is to follow them throughout their entire career.

Number two is that it's based on the recommendations.

The category C -- there's only one, and that's a nutritional question. Everything else is an A or a B.

And to realize that we have now an automatic format so that the core questions is (sic) really 40 and can drill down to up to 145.

And the timeline, when you take it electronically, is less than 20 minutes.

So what I'm trying to suggest to you is the instrument that we're wanting to work with within the Air Force and that we're ready to send to TMA next month is the HEAR-3.0.

This is where our sources came from.

This is really where we've struggled in the Air Force. Our sister services have a lot longer time for basic training than we do. We have six weeks, and we're going from 36,000 at Lackland to 54,000 in the next two years. We have a tsunami of young people coming.

When you get washed back, it's because you missed your train by hours, not by days, not by weeks -- by hours, and you had to recycle if you lost time in those hours.

We've also looked at the mental health -- and I say that 'cause the last slide actually changes on your handouts a little bit. We actually have a mental health evaluation when they first come in so that we can actually identify those individuals that need further evaluation. Everyone gets a general survey in the mental health area -- behavior health issues, and if they fall out in certain questions, then they're identified, then they take a more in-depth instrument to see if intervention needs to be made.

So it's not something we ignore. It's something that we actually try to address and provide intervention guidance early on.

We've also looked at the kind of troop we're getting. Now, for me, I can't say what it's like at Great Lakes or at Fort Jackson for somebody in the first week, but in the Air Force that first week we strip them down pretty good -- emotionally, mentally, psychologically. We're undoing the paths that they brought, and we're starting to create airmen who will be good troops, a part of the team for years to come, and it's a very intimidating, very difficult time.

Our suicide gestures, our suicide completions are far, far greater in the first two weeks. It's like night and

day, two weeks versus the other four -- just because it's a very intimidating experience, very difficult time for them as people, and we recognize that, and that's why we deal with that.

So when I met with the folks in the Air Force, we really did sit down and say, "What is the best time to implement the kind of instrument that we're looking at?" And we actually looked at our brief BMT -- our basic military training time, and then we looked at our technological training time, and we decided that our best opportunity to -- in a less intimidating way -- is to provide the instrument to them when they first hit, first sign at their tech training bases.

Now, you may say, "Well, that's a different population." Well, it's really not. Somebody who's six weeks over. In fact, the slides that we saw earlier -- maybe one of those slides would have been different six weeks later in terms of your alcohol -- recent alcohol use and things of that nature.

So we really don't think we're losing a lot of good information that would help us help them.

But at the same time, what we do get once they hit tech is information that we can turn back and give back to them because there'll be an automated format, as we currently do.

The HEAR's been in the Air Force now for five, six years. When I go to the new location, I take the HEAR once again, and I get in the mail a summary report, and my doctor -- when I see my PC, I have some information to talk to me

about, whether it's cholesterol, blood pressure, what have you.

So as we struggle with this -- and believe me, we really did -- we finally defaulted and say, "No, the best value for serving our people is to begin to introduce it during tech training."

And my last slide is this -- it's really our summary -- basically, what we're saying at this point at the Air Force is that we're looking to do the HEAR 3.0, then we'll go to TMA in March for their input, for their guidance and review.

We're looking to add a trainee health module to it that will cover the kind of questions that the HEAR 3 does not cover.

A 35,-40-year-old, would find a question that deals with their early childhood maybe not as meaningful as if they are 17, 18, 19 years old, and we realize that.

So what we're wanting to do is to add to our 3.0 trainee health module that would affect those individuals at that particular base but would not be a part of the HEAR as they would see it later on because they're no longer in that category, and yet we would have captured that data early on when they first took it.

That's my brief. Any questions.

DR. OSTROFF: One quick question for you.

LT. COL. McKNIGHT: Sure.

DR. OSTROFF: If -- as you indicated, if there are

problems with suicide attempts and suicide completions in the first two weeks of training, you don't administer this until the end of training, then how do you have any information about what was associated with the risk factors for why that occurred in the first two weeks of training?

LT. COL. McKNIGHT: Well, the process that we do in terms of evaluating them early on is addressing that great concern.

The issue for us, really, is how to link that data up to -- take it forward, so to speak, so that it hooks into the HEAR 3, so it goes into the training environment -- the tech training environment.

And that's certainly something that we're talking about right now because we know it can be done.

We have really -- this has been a very difficult brief to put together in the sense of wanting to fall into line and say we're locked in step with our sister services, but really we were not able to do that, and that might -- a good question, sir, and we will be looking at that.

DR. OSTROFF: Greg?

DR. GRAY: Greg Gray. I have to say that I'm very troubled with what I'm hearing today. We have a scenario where we have a goal to use data that we collect when people enter and hopefully aggregate it to get at some of the risk factors for various different things.

And yet I'm hearing that the services are all going in different directions -- different directions with respect to questions, different directions with respect to time of administration and different approaches with respect to how to present those questions, whether it be a palm pilot, a computer terminal or a paper questionnaire.

I think epidemiologically this is really defeating the whole purpose of the RAP -- the central purpose, anyway, and we need to probably wrestle with the differences here.

LT. COL. McKNIGHT: Well, I think -- what I'm excited about is you have now a variety of perspectives that each one of us have really struggled and given you our best opportunity to see where we can -- where our needs are or how best we can serve our folks.

And so the recommendations from this board will actually be very helpful for all of us in that regard.

DR. OSTROFF: One more quick comment and then I don't know if you have any comments.

MR. GOODRICH: Sir, my name is Scott Goodrich. I'm from Tricare Management Activity, and I'm the so-called Army expert here that my colleague referred to.

I'd like to correct a quick misconception, and that is the HEAR is not an Air Force project, not an Air Force initiative anymore. It is now a Tricare initiative and being handled at a tri-service level by a number of experts sitting up

in a working group at Tricare, and we are in locked step with my other colleague, Dr. Wah, and the CHCS-2 clinical data repository.

We have a number of items on our plate that are very germane to this discussion, and I've been kind of holding my piece until now, waiting till all the presentations have been made, but we have always been very strong advocates for the Recruit Assessment Program in its conceptual stage in that we definitely have to gather that type of information at the beginnings of a serviceman's or servicewoman's life cycle within our system and then beyond.

But we also recognize very strongly that, although the RAP may gather baseline health assessment as we go through a military career, baselines tend to change and that what you want is information that is proximal to a point of deployment -- that is really what we're all about.

What we are doing is coming up with a set of questions, and indeed 140 misrepresents us somewhat.

We have managed to bring the average question burden down to about 60, and many of the items that we are currently targeting with the HEAR are very similar to those that Dr. Hyams has put together for the RAP.

However, in previous discussions, we have shared questionnaires, and we both recognize that at some point in time we are going to have to sit down and standardize many of the

questions that we ask because to follow information about an individual's health over time and be able to compare questions over time, you really need to be asking questions in a similar way so that you need one set of core questions that can be repeated at intervals throughout the service member's life cycle.

So we understand that this is something that's going to be very important for us to do to make this a successful surveillance initiative.

The other thing that is very, very important to us as we move forward is that all this information ends up in one clinical data repository and that is the clinical data repository for CHCS-2 that Colonel Wah -- I'm sorry -- Commander Wah will be speaking about in a few moments.

That is critical in our mind. That is why we are focusing very, very tightly on the automated solution using CHCS-2 and using an MHS electronic health portal that will improve our access, so this can be managed through the Internet and all data maintained in the clinical data repository.

And I understand we are short for time, so I will simply say I am here for further questions regarding the HEAR and regarding self-reporting tools at the DOD level and how we might integrate to form a greater whole in the future.

DR. OSTROFF: Thank you for your comments. I share Dr. Gray's concern greatly and one of the -- I mean, the issue basically before the board is: Do we support the RAP, and

as we move forward to move it from a pilot program to an operational program -- how do we do that in a way that isn't the proverbial epidemiologic nightmare which is garbage in/garbage out?

You know, in addition to wanting to monitor things in the Air Force or monitor things in the Navy or monitor things in the Marines, one of the objectives is to compare across services, and the only way you can do that is with some sort of standardization -- I'm sorry.

And that's going to have to be the way. I mean, I can't see the board making recommendations that everybody can go off on their own and expect to have something that's going to over the long term be useful.

CMDR. LUDWIG: I have a quick "yes" or "no" question.

DR. OSTROFF: Yes.

CMDR. LUDWIG: Is there a plan -- I think this would be maybe to Commander Ryan -- is there a plan to include officer accessions in an assessment -- initial assessment program?

(No audible response.)

DR. OSTROFF: Okay, let's move on to the last presentation -- that's Commander Wah.

CMDR. WAH: Thank you. I'm Robert Wah. I'm a physician, double-boarded in reproductive endocrinology and

OB/GYN, and previous to this current job, I was working on the population health ingration (ph) team at TMA and learned a lot of population health from people like Scott Goodrich and Kelly Woodward over here.

Prior to that, my only population health was contributing by making more population as an infertility specialist.

(Laughter.)

CMDR. WAH: That's also how I got involved with CHCS-2. We found that CHCS-2 has been a very good tool for doing population health, so my work when I got on the team was to sort of dive into CHCS-2, went down to Portsmouth to see how it was working at the test sites down there.

What I would like to do today is talk about how CHCS-2 can interface with some sort of a Recruit Assessment Program. I don't want to get into the areas that we already spent a lot of time talking about, about the different needs of the services.

So if I could have the next slide -- I stole this slide after seeing it yesterday from Commander Ryan. She had this in her millennium study. I think she called it the cradle-to-grave longitudinal health study.

If I can -- incidentally, it just happened to coincide with one of my other sides, so I stole it yesterday and put it in, but she started about talking here at preinduction and

going all the way to discharge.

If we can go to the next slide, I put this in to talk -- I'm not as grave -- or cradle-to-grave as she is. I call this my "circle of life" slide. I mean that because I have a four-year-old, I guess.

(Laughter.)

CMDR. WAH: But we have here is -- the way IMIT looks at our information systems, how we can support the mission of our operational forces, and so what we have here is our obsession -- you know, this is the way most of our Navy and Marine Corps recruits look when they come in -- as you can see with the briefcase and suit.

They come into the system here; we train them; we deploy them; they go out in the field. If they get hurt, we take care of them out there. If they have to come back in the theater -- from theater we have a way of keeping track of them which is called TRACES.

When they're out in the theater, we have this theater medical information program that encompasses a number of systems that are both logistically involved as well as medically involved -- I don't want to go into that, but out here but we have a CHCS-2 theater plan that looks and feels the same as what we use in Garrison.

So the way we train is the way we fight, so no matter what system we're using -- whether you're in Garrison or

you're out in the field or you're deployed, it'll all look the same for our practitioners.

And then, as Colonel Goodrich talked about, that's all going to feed the clinical data repository.

Now, when they're out in theater, there's going to be an interim theater repository, and it may be even down to a laptop in terms of maintained data until there's communication with these various data repositories.

But this is -- I just wanted to show this, and obviously it comes out at the very end when you come back out of theater to our garrison MPF's or when you leave the service and you come out to the VHA -- VA Center here.

This is also, I think, Captain Doctor Hyam's life chart here since he started here in the Navy, and he's come all the way around back out in the VA out here as well.

(Laughter.)

CMDR. WAH: So I thought this chart really looked well for this.

But I wanted to give you a sort of overall presentation about how we view what we're going to be able to offer in terms of IMIT for the military services.

So -- and I wasn't sure about how much familiarity people had with CHCS-2. I heard a number of comments during the discussion this morning about CHCS-2, and I feel that I have to spend just a moment or two talking about what it is -- CHCS-2 is

because some people confuse it as a little bit better than CHCS-1, and I would submit that it's a lot better than CHCS-1, so when you talk about --

DR. OSTROFF: It better be.

(Laughter.)

CMDR. WAH: Well, I'm hoping that this group would find it somewhat exciting, so I want to spend, I guess, a moment or two about it.

We're talking about building an electronic -- a computerized medical record, not an electronic medical record, and the difference to me between an electronic medical record and a computerized medical record is an electronic medical record stores text just like a Word file or something like that.

A computerized medical record stores data in a stratified database that you can later go back and mine.

And there's an important difference there, and what we've done is we've worked very hard to make the interface with the provider that's entering the data seamless to that because what we've always had -- and if you think about the way we currently do business in our medical community is -- we physicians -- we write it out on a paper chart, and then, if anybody needs any other information, they make the physician go to another system to provide the information.

Case in point is the ADS system where we want to get clinical people to do business information where they have to

then go code the visit or put down the diagnosis and all that. That requires a separate system from the paper chart that the physician is normally using.

This system, CHCS-2, is going to be our -- where is that thing up there? I must have knocked the lens off here -- but anyway, this is an electronic record that, as the provider is documenting the care that he or she has provided, in the background the computer does all these other things.

So we have -- I'm sorry this pointer is not working -- oh, there it is, okay.

But, you know, it's a very normal interface, just like Outlook. We have folders on the side. We have buttons across the top. And you can build a very legible record that's always available. That's a key thing.

I think in your handout -- we always anticipate if somebody's concerned about not being able to see the handouts very well, so you have a one-page, all-way-expanded view here. Hopefully, that will help you out as well.

But, you know, it's a legible record, and all of this is here is stored as individual, discrete data elements as opposed to just text.

So you can go back and search on the various things that you want.

If I want to know the last hundred endometriosis patients I've operated on and then compare to how many of those

came into the emergency room in the last two years, I can do that, as opposed to dropping a medical student into a chart room and coming out a couple months later with all that data. I can now have the computer do that for me.

So we have one process that does many things for us all at once.

The other thing is an electronic computerized medical record like this also addresses one thing I heard this morning which is security.

We give people passwords and credentials associated with those passwords, so there's role-based security. Depending on your level of security, you get to go different places in the computerized medical record.

A provider will be able to access various things. You can link it down to the specialty of the provider so they perhaps can't see certain parts of the medical record. They don't need to.

But certainly you don't have corpsmen reading who's got sexually transmitted diseases or who has psychiatric disease, whatever, that we currently have the possibility of and certainly see all the time in the paper record.

So role-based security, I think, is another major improvement for the care of our patients, you know, in our computerized patient record.

But anyway, I just want to show you what it looks

like. This is a nice, completed note that really is point-and-clickable fairly quickly. A lot of our people that are using it at our test sites are very quick with this now, and they can generate a note in really just a few minutes as opposed to sometimes writing it out because we can have the computer do all the pertinent negatives as well as describe the pertinent positives.

And what I wanted to do also was show you a module that we're working on currently as a possible way to address some of the things that you're all talking about here.

There is a module here called patient questionnaires, and we built this -- I think we built it just at the middle of January for somebody else, just to show them the possibilities of what you can do, and what we did here was we quickly built this -- what we call self-reporting tool here, and you can see -- you know, there's a series of questions, and you just go through and click on this and answer these questions.

This data then gets stored in a clinical data repository for later retrieval out of the system.

And you can use the computer to do that as opposed to other mechanical or manual ways to do that.

But this didn't take any time at all to build, and so this module is currently in development and should be in the next iteration of CHCS-2, where we'll be able to allow people to build individual questionnaires that they have to have for school

physicals or other things, and it can also be adaptable to something very similar to what I see being built in the Recruit Assessment Program.

So I wanted to show you a little "look and feel" of the program and talk a little bit about that and also tell you that I think I heard another comment that CHSC-2 is that train that's always out there and you never quite catch up to it or it never catches up to you or it never arrives at the station, depending on how you're going to look at the direction, I guess.

I've been involved with this since last March, and so I don't have the whole history of it, but it's currently just finishing what they call GIAT which is Government Installation Acceptance Testing. It finished last week. I think it went fairly well.

The next step is for the services then to write their letters of acceptance or non-acceptance, and we're optimistic that they'll accept it for testing, and once that has occurred, then it's going to go to operational test and evaluation, and that'll take several months.

And the current target is that we'll reach milestones 2 and 3 at the end of June of 2002.

If we reach milestone 3 by the end of June, then we'll start worldwide deployment relatively soon after that.

And it's a fairly ambitious plan to get it rolled out worldwide in about a three-year period.

So that's kind of where we are right now. We're testing it at four sites -- Portsmouth Naval Hospital, Langley Air Force Base, Seymour Johnson Air Force, and Fort Eustis in the Army.

There's about 100 people using the system per day; about 400 patients a day are being seen. That clinical data repository that I showed you -- that first slide -- that currently has about a million records in it.

So the idea is that's going to be our gold mine which we're going to be building with this record, and then you can go mine that electronically afterwards.

So I just want to give you a quick update on where that was before I talk more about how we're going to interface this with the Recruit Assessment Program.

So, given that background about what CHCS-2 is, I think there's a number of things that you need to think about, and I think a lot of them have already been alluded in the discussion we've had up until this presentation.

You know, intraoperability is an important aspect here. We must make sure that our systems talk to one another and they're not isolated.

What I saw when I initially read the review or the background papers on the RAP was that we're establishing these little access databases at each recruit center.

Obviously, that makes it problematic because it's

hard to link those access databases to one another, to be usable in any kind of central way.

Scaleability is another major factor. Access database is take. You can keep track of your recipes at home or your CD's in your file, but it's not particularly good when you're trying to take care of all your recruits across the NHS.

So there's going to be a size problem with this. The program just can't handle that size of a database and still function normally. So scaleability is an important thing.

Security's going to be another thing that's important, and I think some people alluded to that as well.

We want to make sure that the data that's in there is secure and there is some sort of a tracking mechanism to see who's looking at that data. Otherwise, we're going to have trouble collecting that data if people aren't comfortable that the data are secure.

Configuration management -- I think we've had a long discussion before I've gotten up here talking about configuration management, but I will tell you this is one of the biggest challenges we all have in talking about any kind of centrally managed system.

We have to agree on a central set of configuration things so there aren't 12 different flavors of a ceratin program because intraoperability and communication are all going go away if we have that because right now CHCS-1, for instance -- there's

104 different CHCS-1 sites.

CHCS-1 was developed in an era when that was the current architecture. It's causing all kinds of headaches now because there's 104 different ways to name various things.

If you want to talk about, you know, down to the level of configuration management, currently, if I'm at an MTF and I have a certain pill that I like, I can name that pill Dr. Wah's blue pill, and it will mean a lot to that CHCS system because I can link it to the National Drug Code and all that kind of stuff.

But any other MTF that sees Dr. Wah's blue pill won't know what that is because it's all local to that one CHCS-1 host, and that's a huge problem that we have to address all the time.

And I think it's going to be another problem for the Recruit Assessment Program as you've all just been discussing here, talking about the different flavors the various services want, the various recruit centers want -- location-specific questions added.

You're going to have to wrestle with that, and I don't even want to start having to work with you on that one because we have to do this all the time.

But I will tell you that's going to be one of the big obstacles to overcome in this process.

Data quality -- you know, there's going to be a

need to make sure that the data you're getting is the data you think you're getting.

When I looked at this form that we were given out here, one of the things I noted is that you have sections, and each section has various numbers of questions within the section.

Well, you have duplication of the question number, so there's question number 5 in each of the sections.

And so it's very easy to do data crossover in those kinds of circumstances that can corrupt your database.

So it'll be very important to make sure that that data stays clearly stored accurately.

We've seen problems like this in CHCS-1 where we've asked non-medical people to say, "Okay, in CHCS-2 we want a field that lists the creatinine." Well, to get something in the CHCS-2 currently, it has to go to CHCS-1 to pull it.

So they programmed it to go pull the creatinine out of CHCS-1. Well, there's serum creatinine; there's urine creatinine; there's creatinine clearance. To a non-medical database engineer, they don't know the difference, so they either pick one because they don't want to bug the doctor and ask him what the difference is, or they'll give you all three, okay?

But nobody necessarily goes back and checks that, so when you're pulling up CHCS-2 and you click on "Show me the creatinine," you've got to make sure that what you're seeing there is what the original source data was supposed to be.

The same thing when you have a questionnaire like this that has multiple question number 5's across 12 sections or how many other sections are in there, so you've just got to be very careful about building a questionnaire and building a database in terms of your data quality.

So in terms of possible next steps that I see in terms of integrating whatever Recruit Assessment Program you all decided to come up with, I kind of elicited some things that I see as necessary next steps to put it into CHCS-2 if that's the way you want to go with it.

First of all, you've got to define your requirements, and I think there's already been a lot of discussion about how hard that's going to be, but you have to define your requirements -- have to agree -- tri-service, across all services, to what these requirements are and stick by that agreement.

And then refine your teleform if that's what you choose to use.

I want to also mention that there are a lot of other data entry modes, and those have been discussed, I think, a little bit, whether it be a hand-held or a terminal -- sort of a kiosk. That little questionnaire that I showed you -- we could module that out so that that's the only part that's there on the screen, and a patient could come in and fill out that or a recruit could fill it out.

Once it's supported like that, it could go to a web-based format across a secure server; it could go to a hand-held -- any number of ways it could be a data entry point besides the teleform.

I think somebody was complaining that the teleform is labor-intensive. There's little shards of paper that come out when you pull the spline (ph) off of them. Obviously, those kinds of things could go away if you had another data entry.

So either refine the teleform or consider other data entry modes is my recommendation -- to look at some of the other technologies that are out there. There may be other ways to speed up the data entry process that makes it cleaner and easier.

And then whether or not you import the information to the CDR now or later is another decision I think you have to make.

You know, people have always this anxiety to have something today. "I need it today; I can't wait for whatever is coming down the road, whether it be CHCS-2 or the next iteration of the HEAR."

If you were to do that, you have to kind of be thinking about how you're going to integrate your database with the CDR at a future date.

Up to this point, I don't -- I've talked to the people who have been involved with CHCS-2 for some time, and even

though there's been a number of slides this morning that say the RAP will be integrated with the CHCS-2, I have not heard anyone define that requirement for us at the central office level, okay?

And that's really what we need to have. It needs to be -- a defined requirement has to be given to the central program office to -- and we have to go then and budget to do this.

You know, the word we have in our office is we can do anything; it just takes time and money, neither of which anybody has.

So we need to know about a requirement, and as far as I know, the requirement for integrating the Recruit Assessment Program has not been given to the CHCS-2 program office.

So if that's something you all decide you want to do, we need to get a defined set of requirements that we can then cost how much it's going to cost to integrate into our database in the clinical data repository, and then we've got to work on figuring out where we're going to get the dollars to do that work.

So with that, I'll stop here, and I appreciate the opportunity to address you all, and good luck with the remainder of your discussions, and I'm happy to help with any technical questions that might come up.

DR. OSTROFF: Thanks. We're running a little bit late, but I did want to have about five or ten minutes of

discussion now that we've heard all of these presentations and get some feedback from the board.

I mean, from my perspective, it seems that you have here, if I understand everything correctly, this is what Congress wants you to do; this is what the IOM wants you to do; this is what the board thinks you ought to be doing, and -- and I think there's little question that this needs to be operationalized. I mean, it needs to go beyond the pilot period and it needs to be operationalized, and I think -- you know, number one, somebody's going to have to pay for it, and that hasn't been discussed as to where the resources are going to come to do this.

And I mean, if I was the one paying for it, I'd want to make pretty darn sure that it's being done right.

And I think that's going to require some standardization. I hate to say it, and it's going to require -- this isn't one of those situations where everybody can sort of take the recommendations and then operationalize them as they see fit from service to service to service. Otherwise, you've lost the intent of doing it, and I don't know -- that's just my thought. I don't know if anybody else has any thoughts about it.

AUDIENCE MEMBER: I wanted to bring a couple points up. First of all, going back to the questions, the question was -- is this a -- is the RAP as it exists today an

effective tool for collecting baseline information? And then the issue of feasibility at the bases.

Understand a couple of things. From a policy standpoint, we're not looking for these questions to drive keeping people from joining the military.

That's not the goal of this process by any means, and that's a whole 'nother realm that we talked about from the standpoints of MEPS and medical entrance processing and what waivers are given and what are the restrictions. This is not where we're going with this type of project.

From the standpoint of policy, the recommendations that you bring to us will allow us to take that next step.

Right now we're still in a pilot stage. We've been there since 1997.

If we get recommendations to say, "Go forward," then we can start talking about palming for this, talk about functional requirements, laying the pieces together and bringing this to the attention of Dr. Winkenwerder and Dr. Chu at the level of the undersecretary of defense -- personnel and readiness.

So now we've crossed this line from the medic side of the house to personnel.

And with that comes the money and the whole process of making this so.

So we convince our leaders of it and everything

else to fall into place.

That's why we need your recommendations; that's why we wanted to present this from all sides and allow all of the services to have input as far as the questions are concerned.

Certainly we have a product right now, from my mind, that collects baseline data. I'll leave it at that.

DR. OSTROFF: Well, based on what we heard yesterday, maybe we ought to make it look like a Nintendo game.

(Laughter.)

DR. OSTROFF: That's what they all seem to know how to do.

(Laughter.)

DR. OSTROFF: Yeah?

MR. FRIEDL: I think what the board's been asking for, though, what came out in some of the questions were sort of related to where are we in this pilot-testing phase.

And what I haven't heard in the presentations is something that tells you about the effectiveness of these questions, and we've got to get down sort of into it and -- you know, there are questions about the reliability, for example.

We're asking people, "Have you committed a federal crime here?" when we ask about, you know, anabolic steroid use, and you know, maybe some of those questions, you're not going to get reliably answered.

We're asking them, "Do you have an eating

disorder?" And they're still -- you know, in the first three days here of recruitment -- they can be thrown out, even though we're not using this for selection -- as an EPTS, you know, and that's, you know, something that falls in the medical standards.

There are questions -- you know, I mean, the concept -- some of these things like the psychological baseline questions, we're just not going to be able to do too much piloting.

We have to put in solid questions there that we can use for post-deployment comparisons and future -- sort of go-for-it illness situations.

It's incredibly important that we do this, and we've heard lots of discussion on, you know, it's important that we do this, and everybody wants us to do it, but we're still talking kind of at a conceptual level, and I think what I'd like to hear more about, and I think what the board's asking for is show me, you know, where's the beef here.

DR. OSTROFF: Well --

MR. FRIEDL: Do we have results?

DR. OSTROFF: Yeah. I mean, from my -- I partially agree with what you're saying; however, I think that there is a fairly large science behind asking these types of questions.

I mean, it's not -- I realize the military is a unique setting, but you know, if you are asking somebody if

they've ever driven a car while drunk, that's not, you know, something unique to the military, and others have thought about this and how to ask that particular question.

And I don't think it's -- I mean it's not going to be acceptable, at least to me, to spend another five years trying to operationalize something like this when you've taken five years in terms of trying to pilot various aspects of it.

If it's the right thing to do, let's do it, and, you know, just like Dr. Winkenwerder was talking about some of these vaccine issues, I mean, I think that this is an important activity, and we ought to do it, and we ought to do it right.

Bill and Dr. Patrick.

DR. BERG: I awhile ago was prepared for -- I was going to ask the question, "Okay, where do we go from here? Where's the timeline?"

And it seems to me we're sort of at a dead end in the sense that we've got little pilot projects all around, and we've heard repeated assertions about autonomy and why it's important.

And Kevin has put together a nice, little VEN (ph) diagram, but I think that tiny area where all the systems overlap just gets too much wiggle room.

You know, it seems to me the next decision is to say, "Okay, here is the one way we're going to do it," and then move forward on it to the next set of questions, but I don't see

much sense in continuing all these different projects and reporting back to the board in another six months or a year.

DR. PATRICK: Well, again, I think what we've found with these projects -- these pilot projects -- is that this is a complicated process, and I'm wondering whether we couldn't find a way to take the value from each of these pilots and get to some common set of requirements.

I mean, the important issue here really is to establish a process of ongoing assessment, not to put forward right now a set of questions that would be asked. It's to put in place a process that will support the refinement of these questions.

We know that these are going to be fairly malleable over time. We already know. We've already looked at these and found grammatical errors and ask it this way and ask it that way.

What I'm struggling to hear here is how is there a way in which we can take the value of these pilots and in an accelerated fashion and as accelerated as anyone would want get the value from all three to really approach this?

I mean, it would seem logical that each one of the services may, in fact, have their own questions that they would want to ask, but that there is this center area on a VEN diagram in which the overlapping services could ask core questions -- core questions that everybody should be asked, and I

like the notion that it's not just on entry; they should be asked appropriately over time so that we know the natural history of many of these risk behavior issues.

But how can we -- I guess is there -- is there a policy directive that can cause a time-certain process by which the requirements for establishing this could occur, and very importantly, the presentation from Commander Wah there -- how this, in fact, then going to be linked with this clinical system that I assume is taking an awful lot of investment?

You're saying that it's a three-year roll-out, and by the end of three years, what is the projected number of users of the CHCS-2 at the end of three years? Would this be accepted?

CMDR. WAH: Yes, it will be.

DR. PATRICK: Is that essentially then going to become the clinical information system that folks are going to use?

CMDR. WAH: Yes. It will be the NHS clinical computerized patient record.

DR. PATRICK: Amongst all services.

CMDR. WAH: Yes.

DR. PATRICK: A critical issue that we've heard here, then, is that nobody who's been developing this has talked -- and you're heading up this initiative; is that right?

CMDR. WAH: One of them.

DR. PATRICK: One of the lead people.

CMDR. WAH: I don't want to have that target painted on me.

(Laughter.)

CMDR. WAH: But you know, any big system like this -- one of the -- we have what we call a spiral development process where we take in requirements and we have to cost them out, and then we have to budget them.

And you know, way before I got to this program, a core set of requirements were established, agreed on by all the services; they costed it out, got the money and started building it.

We currently are in the final stages of testing it before deploying the first version of this.

But what requires -- in a spiral development process is, as new requirements come in, they have to be identified, agreed upon, costed, and then built into the system.

But, you know, the plan is -- is that we are going to have this CHCS-2 clinical data repository, computerized patient record deployed across the MHS in a fairly rapid way.

Now, at the end of three years, the last one that's deployed, the last one where the place is turned on, is probably going to have a different system, a little more improved system than the form that was turned on first --

DR. PATRICK: Let me put this in the form of a

question. Would it not be possible to align the requirements process development -- that process to develop the requirements of the RAP along with the process of developing the core set of questions that are expected to be asked?

CMDR. WAH: Yes. I mean --

DR. PATRICK: Those questions, probably by the time they're implemented, will change.

CMDR. WAH: And to some degree, the exact questions --

DR. PATRICK: Right --

CMDR. WAH: -- don't have to be defined at the time the requirements are --

DR. PATRICK: Right.

CMDR. WAH: We need a requirement that says we would be able to like to put this kind of information --

DR. PATRICK: Right.

CMDR. WAH: -- into the clinical data repository. This is the vehicle in which we envision it going in 'cause, from our standpoint, if there's 100 questions or there's 100 questions, I don't think that makes as much difference.

But if you want to bring it in on a scantron form or you want to bring it on a palm pilot or you want to have a tablet or a kiosk or something like that, then we need to know about that, although the system has some flexibility about how it receives data.

Still, the other critical element is we have to know how we're going to map the questions that are asked so that the answers are mapped to the clinical data repository.

DR. OSTROFF: Right. Let's take a couple more. Colonel Woodward?

LT. COL. WOODWARD: Yes, thank you. Kelly Woodward from the Air Force. It would be helpful, I think, in moving this along if the board wanted to address one issue that we're getting at, and that is -- is the scope of the RAP -- is it intended to be capturing baseline information at the point of accession as a snapshot in time, or is it intended to be our longitudinal health assessment tool because we actually have a program office -- a tri-service program office that's been grappling with the longitudinal recurring assessment process through the HEAR which has been going on for a number of years working in a tri-service venue.

There is policy, by the way, written -- HA policy directing the use of the HEAR unless it's sundowned -- I don't know if it has or not -- so I think it would help us to know whether the RAP includes the ongoing surveillance tool or if there are two separate things because that would then help us know programmatically how to proceed, and I will just say programmatically -- two programs is probably sometimes harder than one.

DR. OSTROFF: Let me just say -- I mean, maybe I'm

wrong, but my vision was that you wanted some sort of a baseline assessment tool that could then be used to determine outcomes over time amongst accessees.

And I -- I mean, from my perspective, I don't really care if the subsequent assessment tools are exactly the same as the one that's used on accession.

But I do care that the one that's used at accession is usable and is -- is standardized.

And I mean, I haven't heard anything yet that tells me that this isn't feasible, and you know, if it's an issue for the Air Force with the six weeks, make it six weeks and one hour. I mean, if we think this ought to be done, do it.

LT. COL. WOODWARD: And that's helpful, sir, because I think, if that's what the scope of this is, then some of the discussion about this -- is this just a baseline snapshot in time or is this the foundation for the ongoing questions -- you know, we may approach that differently.

DR. OSTROFF: Let me turn to Dr. Herbold, then we can --

DR. HERBOLD: I think the board can help. I think there's short-term objectives here and some long-term objectives.

I think the board can respond to what we've heard here on some general principles that the board holds dear and supports.

One is, when should it start, and it seems to me

that, if it's a recruit assessment tool, it ought to start with recruits, not when you're in secondary training. That's a principle.

Another principle that I heard that I like is this concept of -- there's a dataset that's needed, and there might be some different ways of getting there, but there's a general set of information that needs to be in this.

But then counter to that there are general principles of survey management, conduct of surveys and collecting data that we feel it's important that it be similar across all services because the issue of what happens to a side is one thing -- physical injuries and those things -- what happens in the recruit training environment is a very, very important issue to the services and to the public.

And then also, if you need to have that standardized entry information to be able to adjust for any differences in those populations as you follow them forward through their careers -- so I think that we can respond to what the general principles are and the one most outstanding one -- or the two was that it ought to be done in the same way and started at the same time, and then we can wrestle through some of these other issues.

I was there with Trimest and all the -- you know, the information management thing is a moving target, a moving train, that's always going to be changing.

DR. OSTROFF: Well, I'll state a third principle which is that it has to be epidemiologically sound.

I mean, if that doesn't come out of this board, nothing will.

Please make your questions brief, or else we're not going to eat.

MR. GOODRICH: I will, sir.

DR. OSTROFF: Or your comments, I should say.

MR. GOODRICH: Scott Goodrich, TMA. Just to add to what Colonel Woodward just mentioned, the tri-service, tri-care here is going to probably be ready to start collecting information in October of '02, just the beginning of the next fiscal year which means that we will be gathering information that will be going into the clinical data repository.

Now, we understand that for the RAP that, if we were to use something like the HEAR which has been designed as a core set of questions, if we were try to expand that, it would be a fairly simple matter to add additional questions approved by this committee to something like that core set of questions that we'll be using in the HEAR.

Indeed, it has always been our thought that, with that core set of questions that we are going to be putting forth with the HEAR, that the services should be free to add additional questions that are unique to their service requirements, their service needs.

So I think that we can work very well together and also ensure that this data is maintained and that the integration to CHCS-2 continues so that we have a usable instrument in years to come.

DR. OSTROFF: And Dr. Ness, did you have a comment?

DR. NESS: Yeah. I'll try to make this very brief. I think there are -- it occurs to me there are three separate issues here.

One is what's going to be the baseline core set of questions, and how quickly does that get rolled out?

Two is with respect to follow-up questions, how are those designed, and my own personal belief is that optimally those follow-up questions should come from at least a subset of the core of baseline questions.

In other words, to some degree one wants to repeat a set of baseline questions over time. That doesn't mean that you can't add additional questions; it simply means that those formats should be maintained over time.

And then the third one has to do with this information management set of strategies.

And personally I would vote at this juncture that, with some minor modifications within a fairly short period of time, that the RAP gets rolled out with the opportunity for the services to add questions that the follow-up set of questions can

be, you know, kind of a next stage of the piloting process and that the information management requirements obviously need to be taken care of also within this very short period of roll-out.

But, you know, I see no reason to kind of continue this process ad infinitum.

DR. OSTROFF: No. Last comment, and then I'll let Greg have the last word if he has any.

MAJOR GOULD: Yes, this is Major Gould. I'm USIS preventive medicine resident. The one other point that I heard and saw three or four different versions of is -- aside from the question of question content administered to each of the different services, but also the question of how the questions are administered, the pictures that Dr. Young showed of large groups of Marines all sort of hanging over each other versus what I heard another service mention about individual study carrels allowing for the lack of leaning over and so forth to questions on palm pilots -- I mean, that needs to be standardized as well in addition to the actual question content. Thank you.

DR. GRAY: Just a couple of very quick things. Let me just say that the RAP developmental team was never tied to any particular type of technology.

We chose the paper-and-pencil format because it had been pioneered with the SHIP program and it worked. Also, it gave us the flexibility to change our questions on the fly. We were able -- not over a several-week or several-month or several-

year period -- pilot new questions and come up with really the best sort of questionnaire possible in a short period of time.

So that's the reason we chose that technology, but certainly we're not tied to it over the long run.

I think, as far as early separation, I think any kind of baseline assessment has to be totally separate -- early separation.

Lieutenant Kaforski -- he was really talking about the SHIP program and not RAP program as it's been -- if you expect to get accurate data, it's got to be separate from early separation.

If the troops feel they might be relieved from the service because of some question they answered, then they're not likely to give accurate responses.

If we ask something that seems to ask something that possibly is illegal like the use of the steroids -- I'll have to look at that question -- maybe that question should be modified or removed.

But it really has to be separate -- the baseline assessment from early separation.

Another thing is we spent a lot -- you know, a number of years now trying to optimize the sort of questions that you would ask recruits, the sort of baseline data that you need, and we really think you have a good instrument. I mean, it needs some modifications, some changes in language, but we feel like we

have a good instrument.

And it has to be compatible with the later HEAR assessment.

I mean, for you to have longitudinal database, you've got to start with baseline, and you've got to update it over time.

But some questions do not have to be asked again. Once you ask about childhood trauma, once you ask about occupational exposure before you entered the military, you don't have to ask those questions. Those are out of the way. You don't have to go back to them again.

And so your later questions like the HEAR will be much simpler.

I think the last point I'd like to make is I don't think the HEAR really fits the bill for baseline assessment since it's a different type of tool. It's been designed for medical intervention, for people who need some sort of health care during their military service.

It can collect longitudinal data; it can update the database, but it's really not set up to collect the sort of baseline data, the sort of onetime data that you need to build on to have a longitudinal database.

So we have to sit down with the HEAR people; we have to make sure that the RAP is compatible with the later data that's collected in the HEAR. I don't think the HEAR really is

suitable for collecting baseline data amongst recruits.

Commander Ryan can say something to that. Anything you want to add to that?

DR. OSTROFF: But it's taking away from mealtime.

(Laughter.)

DR. OSTROFF: Okay, let's adjourn for lunch, and we have to be back at 1:00.

(A lunch recess was taken at 11:54 a.m.)

AFTERNOON SESSION

(1:09 p.m.)

DR. OSTROFF: Let's go ahead and get started. People are still filtering in.

We have a couple of presentations in this next session concerning a topic that I personally don't know a tremendous amount about, and that's Phased Array Radar, but there are clearly some issues related to the facility in Cape Cod, Massachusetts that there are formal questions that have been brought before the board, and we're going to have a couple of presentations to try to bring the board up to speed on some of these issues.

And so why don't we go ahead and get started. Colonel Ruscio is going to initiate the discussions.

LT. COL. RUSCIO: Yes, sir. Thank you. Good afternoon, ladies and gentlemen. I appreciate the opportunity to present to you this afternoon.

What I would like to do is just give a brief overview, present the questions, and then following on my presentation there will be some presentations that go into a little more detail on the subject.

So I'll introduce the issue, provide some questions to the AFEB and would like to spend a little bit of time on the background and concerns.

Phased Array Radar -- the Phased Array Radar at

Cape Cod is one of three radar systems in the United States that protects the United States from intercontinental ballistic missiles and sea-launched ballistic missiles.

Phased Array is an electronically steered radar system which is not uncommon in the radar technology. In fact, it's used throughout DOD and commercial industries.

I believe the issue is related to this question here -- approximately two and a half years ago, Air Force Space Command initiated an environmental impact statement for the purpose of upgrading computer systems in the Phased Array Radar system, both the one at Cape Cod, the one at Beale, California, and Clear, Alaska.

As part of that environmental impact system and due to communities' concern on the potential health effects related to low levels of radio frequency energy, the service life extension program and the EIS was -- full EIS was initiated.

Specific questions that we would like to present to the board are the ones that are listed on the slide.

There's considerable concern that the standards now in place for protection of both occupational workers and the communities are not sufficient in providing a standard of safety related to radio frequency energy exposure.

In addition, the second question I'll talk about -- the Air Force's work with the community, the county and the state in trying to work with the community to address the

public health issues that have been raised.

There will be a series of documents related to addressing those questions such as statement of works, approaches, protocols and methodology to evaluating the health concerns that have been raised to the Air Force and Space Command.

I'd also like an evaluation of the -- of any indication for an immediate epidemiological assessment or further epidemiological assessment for the DOD members or the communities involved in this concern, this issue.

I just wanted to provide you a little bit of background. I mentioned already that the Air Force is executing a proposed service life extension program to upgrade the computers and the system so that the system can maintain and continue to run.

There's been a considerable amount of public concerns fueled by various actions and different issues that have been brought up.

Actually, this issue is not necessarily new. You can go back to 20 years ago when the PAVE/PAWS facility was first put into place, and there was somewhat of a shaky start in 1979 -- and similar concerns related to low-level radio frequency energy exposure.

The Air Force did work with the National Research Council. EPA produced a variety of sound -- I think very sound

documents to address those issues.

The PAVE/PAWS facility is located on the upper cape of Cape Cod.

The Massachusetts military reservation is one of the largest superfund sites for the Air Force.

So there's a history of a level of mistrust with DOD related to cleanup issues and health risks.

The other issue is the suspicion that secret data exists with radio frequency energy related to indications of adverse health effects.

There are certain cancers that Dr. Knorr, state epidemiologist, will be following on my presentation with some information on the state epidemiological information related to cancers and some of the studies work that has been done in that area.

We also have a researcher -- the Air Force has a physician researcher who has information or claims information of greater risk and immediate risk to individuals based on radio frequency energy exposure.

The Air Force is working with a variety of experts and a three-pronged approach to addressing this issue.

In September this year, the Air Force has contracted with the National Research Council to specifically look at the one question of operating or using continuous-wave or pulsed-wave radio frequency energy biological data as a surrogate

for phased array Data.

For those who don't know, this has been the process for the past 20 or 30 years, and the issue revolves around power density, not necessarily the characterization or the characteristics of the particular radio frequency energy waveform but more centrally related to the power density.

But we've asked the National Research Council to readdress that issue and to reevaluate that question.

Also, to update the 1979 NRC study -- in 1979, the NRC evaluated radio frequency energy literature related specifically to this and its site and to Phased Array Radar -- excuse me -- and we're asking them to update that study that was completed in 1979.

In addition, we have started a waveform characterization effort. Next week, we'll have a team from Kirtland Air Force Base up at Cape Cod to attempt to evaluate and characterize the waveform characteristics specific to PAVE/PAWS energy to specifications that have been laid out by some of -- a researcher who indicates that the waveform characteristics are of particular concern for health issues.

The Air Force has partnered with the community. We have a PAVE/PAWS public health steering group. It's a public meeting. Stakeholders meet on a monthly basis. We've actually met sometimes more than on a monthly basis.

The stakeholders, the representatives for the

communities include local public health officers, elected and public health officers -- state department of public health and the county department of public health are also on that committee.

The committee has been meeting for approximately a year now, and the committee is going to work with independent epidemiologists from radio frequency energy experts -- measurement experts to evaluate the exposure assessment in the community, to complete exposure assessment in the community and to evaluate that with -- against biologically plausible disease outcomes.

I already mentioned that the makeup of the steering group -- and its attempt to address public health concerns about PAVE/PAWS.

This is one of the areas where we'd specifically like your assistance and your help in moving forward in a sound, science, methodological process.

I think that should be it. What I'd like to do now is introduce Colonel Ashworth who will tell you about the PAVE/PAWS facility.

LT. COL. ASHWORTH: Thank you. Good afternoon. Thank you very much.

I want to take just a second to also footstomp something Lieutenant Colonel Ruscio said. One of the things, as you sit here and hear us brief, you're going to hear a lot of

acronyms, Air Force acronyms specifically. I'm going to clear a little bit of that up.

But also it looks like it has a strong, heavy Air Force flavor to this, and it does right now. There is no doubt about it. You're going to see a big target here in just a few minutes when we show the site up there.

But one of the main reasons that we're here today is to footstomp again the bottom line that, even within the Air Force, out of Air Force Space Command, there's probably 15 different systems that use this type of technology. Across DOD, multiply that even further.

You're seeing potentially a tip-of-the-iceberg-type issue that we felt it was time to expose beyond our command within space command, beyond the Air Force to a broader community because it is getting elevated, and we wanted you in on the ground floor.

We're not really looking for answers here today. Today is for the background to provide you with some knowledge and understanding of what the issue and the questions are and to get you in on the ground level if this escalates.

As Lieutenant Colonel Ruscio said, I'm Lieutenant Colonel Richard Ashworth from Headquarters Space Command. We, quote, "own" this particular system, commonly referred to as PAVE/PAWS, Precision Acquisition Vehicle Entry/Phased Array Warning System. That's what it stands for.

What I would like to do is provide you with a little bit of background on the early warning systems and discuss their radio frequency energy operating characteristics, again to give you a baseline as we move forward in the discussion.

I'll talk to you very briefly about the mission. You've already heard about that.

The characteristics -- some of the health and safety specific issues, some of the survey results and the quick summary.

Mission -- Lieutenant Colonel Ruscio talked about that -- missile warning is first and foremost primary, but also space surveillance. You know, you hear a lot of time with shuttle missions about space debris, size of a dime can be dramatic.

These systems will actually track for space surveillance as well.

The assets -- we already talked about PAVE/PAWS. Also, you'll hear the term BMEWS. PAVE/PAWS are actually at Beale and Cape Cod. The BMEWS -- the Ballistic Missile Early Warning System -- is at Clear, Tulley (ph) and Follingsdales (ph).

The system they all use, the core of their system is called an SSPARS, a Solid State Phased Array Radar System. It is common at all sites, and that is the root of the issue, if you will.

It may be a little bit difficult to see, but on the left it shows you that this particular radar on the East Coast at Cape Cod -- scans for 240 degrees and then in elevation from three to 85 degrees -- has about a 3,000-mile range and tracks an object about the size of a small car.

On the right there, you can see laid out in the green, it shows you the coverage on the Eastern Seaboard of this particular system on Cape Cod.

There is some overlap on the northern and southern ends, if you will, from some of those other systems I talked about, but primarily this is the only system that is the Paul Revere, if you will, of the East Coast.

What you see on the right is the actual PAVE/PAWS site. It's enormous, if you will. It was built in 1978 -- 10 stories tall -- it has two array faces that do the scanning. It has 5,376 antenna elements; only 1,792 of those are active.

You see an antenna element there on the left side of the screen, and as Lieutenant Colonel Ruscio said, you don't see moving parts. You know, when you drive around the airport, you see the scanning-type radars.

This one is electronically steered by controlling the emissions coming from individual elements, and they're able to control it to pinpoint a certain space in time that forms the beam.

The actual beam itself never -- the main beam

never contacts the ground.

Again, one of the reasons is, obviously, it's scanning from three to 85 degrees in elevation, so the main beam itself does not irradiate at the ground level.

But not all of the energy is contained in the main beam. There's a very small fraction, about one one-thousandths of the main beam energy that does slip out, if you will, onto the ground surface, okay, but the main beam itself never contacts the ground.

It operates between the frequency of 420 and 450 megahertz. It has a peak power of 543,000 watts or 543 kilowatts. It is pulsed, and it listens, though, 75 percent of the time. It pulses, actively radiates 25 percent of the time, and then it's listening 75 percent of the time.

So two important points here is the main beam does not touch the ground, and it's not irradiating continuously from a public health standpoint.

From operational health and safety, we of course, like any other service, aren't self-regulating in this area. We comply with this nation's standard.

This one happens to be set by the IEEE, the Institute of Electrical and Electronics Engineers, and has been adopted by the Air Force.

There's two limits there. There's an occupational limit and a general population limit, and it's based on, as

Lieutenant Colonel Ruscio talked about earlier, the average power density.

In this case, for the general population, it is frequency-dependent, but in this case, at the worst case, if you will, it's .28 -- that's milliwatts per centimeter squared, and the thing you have to watch here is the units that we often use -- you're going to even see me flip-flop between milliwatts and microwatts -- it's 280 microwatts per centimeter squared or .28 milliwatts per centimeter squared.

Over time, since 1978, when it was first constructed, there have been numerous RF -- radio frequency energy surveys conducted in and around the facility and several that were actually done out in the community.

The first two there were actually in and around and out in the community, and the thing to really take away from the summary slide is the results over on the right-hand side.

The peak power was measured in 1978 out in the community at any location -- was 19.6 -- that's microwatts -- standard again is 280 microwatts.

The average power which the standard is actually based on -- the highest reading was .06 microwatts out in the community with a standard again of 280 microwatts.

In 1986, at 15 different locations in the community, .28 microwatts per centimeter squared.

The thing to really take away of what we're

presenting here is -- again to put it in perspective of where we stand with existing standards. That's not really what the question is about per se, but we wanted you to understand, as far as the radar operates setting there today, there really isn't a question about its health and safety if you used existing standards.

The question that has been raised is about an alternative theory whereby the current standards don't apply to a phased array-type system.

I chart -- within your handout, hopefully there's a full page there -- it should be readable -- and these are the survey points from 1978 and 1986.

If you see where the two wedges come together up there kind of in the center right, if you will, or top center, that's where the PAVE/PAWS site is located.

The pink wedge or purple wedge is actually the coverage that you're seeing on the upper cape, and at every location measured there it was at least 4,000 times below the current standard out in the community.

On the site itself, it obviously is a little bit higher than that, but in the wedge on and out in the community, 4,000 times below the existing IEEE standard.

So, in summary, we have a system that is crucial to national defense. As I indicated, this system is the only one that's watching the Eastern seaboard.

It meets all current health and safety standards, and the Air Force, as Lieutenant Colonel Ruscio showed, is committed to addressing the public health concerns, and we hopefully are going to introduce the subject to you here today, and you can see how we progress in the future, and hopefully you can be a sounding board to make sure that, as we progress, that we do it in a logical, scientifically valid, public health manner. Thank you.

DR. OSTROFF: Thank you. Can I ask you one quick question --

LT. COL. ASHWORTH: Yes.

DR. OSTROFF: -- that wasn't covered? Was there a particular reason that it was put on Cape Cod?

LT. COL. ASHWORTH: First, I won't have the exact answer to that 'cause, again, those decisions were made in the mid '70s.

My understanding is they looked at a bunch of alternate sites at that time. There wasn't anything particular in the sense that it absolutely had to be there, but when they combined the alternate locations that they looked at -- for instance, there was a site in Georgia that provided similar coverage, if you will.

So there were sites along the Eastern seaboard at one time first that were considered at alternate sites before they sited it, and for whatever reason they decided that that was

the best location.

One thing is it does sit up way on top of a hill. I didn't show all the elevations in relation to geography and everything, but it sets up on top of a hill, and for the most part, you know, you've got the seaboard quite close -- within a few miles.

But there was a system that was put in in Georgia, and I don't know again the history of that and how they looked at it from a national security standpoint about coverage, but it wasn't absolutely -- didn't absolutely have to be there, if that is the question, but it was sited there in the '70s, and now you're looking at probably a couple-hundred-million-dollar investment if you were to move it.

DR. GARDNER: What got it designated as a superfund site?

LT. COL. ASHWORTH: Actually, the PAVE/PAWS itself is not a superfund.

DR. GARDNER: I assume not.

LT. COL. ASHWORTH: It was the Massachusetts military reservation which has a bunch of different activities. There's Air Force. There's guard. There's ODIS (ph) Air National Guard Base, and primarily groundwater contamination, groundwater sites -- is what constituted it being a superfund site.

DR. OSTROFF: Bill?

DR. BERG: Bill Berg. Could we go back to the big map slide and could you --

LT. COL. ASHWORTH: Yes, sir.

DR. BERG: -- show where it is on there? I may have missed it, but --

LT. COL. ASHWORTH: Right there at the top.

DR. BERG: Thank you.

DR. SHANAHAN: Dennis Shanahan. Are you having similar community concerns at your other active locations?

LT. COL. ASHWORTH: Not similar, no. At Clear, of course, in Alaska -- is fairly isolated.

DR. SHANAHAN: Right.

LT. COL. ASHWORTH: The community that surrounds that site is pretty much the people that work at the site itself, and there's very few issues or have been very few issues there.

In Beale Air Force Base in California, there have been -- first, let me back up and say the reason I know this is because there have been what we call scoping meetings as part of the environmental impact statement process -- the EIS process, so we had to go to these communities a little over a year ago and gauge their concern from the public health perspective.

And from that standpoint, it started at Cape Cod with the highest. Beale was next, and then Clear.

And Beale, primarily -- the exposure, if you will, is to on-base residents, not necessarily to the community.

I think the community's five miles or so away. It's not as great at Beale as it is at Cape Cod.

LT. COL. RUSCIO: If I could go back and talk about the Massachusetts military reservation as a superfund site -- I'm the health advisor. That was my original job there, and the contaminants are fuels-related contaminants.

The reservation is made up of the Coast Guard, the Air Force, guard and the Army National Guard. It was a very active base back through World War I. It sits on the sole source aquifer for Cape Cod.

The typical or the standard contaminants at a superfund site related to fuels -- in addition, explosives contaminants -- there is an impact area -- so HMX, RDX -- those -- DNT -- those types of contaminants.

DR. OSTROFF: Thanks. Let's move on to the next presentation, and the next presentation is Dr. Knorr who's from the Massachusetts Department of Public Health. Thank you for coming out to California.

DR. KNORR: It's my pleasure. Thank you for allowing me to address the board.

My name is Bob Knorr. I'm the deputy director for Environmental Epidemiology for the state health department, and I was asked to provide some background on the public health issues on the cape, the work that's been done in the past, give you some perspective.

And what I want to do is discuss that and then I'll end with a little bit about where we are right now on PAVE/PAWS.

I started at the health department in 1986. I didn't have gray hair then.

There are a lot of issues, as Bruce -- Colonel Ruscio mentioned -- there are -- all the branches have contributed to some environmental problems and lots of groundwater problems, air pollution problems with fire training areas; they were burning all kinds of things from excess fuels to PCB's, the artillery and mortar range burning excess propellant that contains carcinogens -- a lot of just mishandling of waste materials, dumping of millions of gallons of aviation fuel on the tarmac.

It's a very sensitive environment, and it led to a significant number of PLUMES (ph) that we've been investigating ever since that period of time.

I guess things kind of came to a head in particular because the department has a cancer registry that released its first report around 1986, and it showed elevation cancer rates for Cape Cod.

And so immediately people were saying, "Well, okay, we've got these environmental problems" that were discovered actually as part of an installation and restoration program on the base, and then we've got all these health

problems, and previously people were aware of the PAVE/PAWS issue and some concerns from the environmental impact statement released in '79.

So they asked us, "Well, are the two related?"

And that's what we proceeded to try to address.

Before you go on -- just to make use of this kind of a slide, you were asking before where PAVE/PAWS is. You can see it up there in the left corner, and there also are a number of nonmilitary reservation issues and environmental issues -- the electric plan is one, but there are a number of others. There's cranberry bogs in that area that will have a lot of pesticide use.

It's a pretty pristine area, you would think generally, but there are some environmental issues that concern people -- and that mauve color, I guess that is -- that's the military reservation in whole, so you can see that the PAVE/PAWS occupies a small part of it.

As a way of background a little bit for the cape, this is a map of the population density. You can see PAVE/PAWS up in the corner.

The area that's shown here is called "Upper Cape Cod." It's composed of five towns. All of Cape Cod is 15 towns. The population of the five towns is about 100,000, and the rest of the cape is about another 70,000 individuals, and you can see the population -- it's not a particularly dense population area.

It's pretty low. It's built up pretty quickly over the years.

And just to show you the coverage that Colonel Ashworth mentioned -- it's about 347 to 227 azimuth, and one of the areas of particular concern is the area of overlap of the beam of the two faces which is -- I think it's about like a 50-degree area there that people are concerned about.

Now, this probably -- this may not be too hard to read -- I thought it would be hard to read, but I wanted to just show this, just to give you an illustration of the various numbers of investigations that the department has been involved in.

It's not just a case where there's one study or maybe a follow-up to a study. There have been a lot of studies on Cape Cod, probably a lot more on the cape than anywhere else on the state.

And in part this is due -- because there are legitimate environmental issues, and there are legitimate health issues.

But the citizens and the activists there are very aggressive. They know how to use the media very well, and we probably -- especially in the early years -- were pretty naive, and what we thought in our early philosophy was -- well, citizens really want us to do this study; we don't think it's really scientifically based, you know, well scientifically grounded to do it, but it'll please them; it'll make them happy, so we'll do

it, and it really didn't work.

We had to learn that the hard way. It's still being learned. We have a relationship -- a cooperative agreement with ATSDR, and we still give them those same moral lessons that they haven't quite learned.

Colonel Ruscio mentioned that the cancer statistics -- just to give you a little taste -- I have volumes and volumes of data, but in 1986 the cancer rates were elevated for about four major cancer types, and it was the four major -- they were the four major types -- that's lung cancer, breast, colon and prostate.

That in itself didn't raise any particular alarms with us. We looked at other environmentally related cancers that we would expect to possibly be related to ground water pollution, air pollution and -- like leukemia and so forth -- and didn't really see a problem.

But the rate -- this is the standardized incidence ratio for two different time periods. The 126 means it's 26 percent above what we'd expect in the state after adjusting for differences in the age, distribution of the populations on the cape compared to the state, and this is statistically significant.

And over the period of time, these years and subsequently, the rates have remained elevated during all this time, so this is total cancer -- we see the same thing with those

particular individual types of cancer.

So the concern has always been there, and so -- so what we tried to do is a way to think of a strategy at the health department to address these, and we had this three-stage approach.

One was to do an occupational study of the military personnel because we thought they might be the most exposed, and the early years in particular -- we weren't aware of how much the contamination left the base.

And the second was to do a residential history study because the cape is known to be an area where individuals retire.

So they may have moved from Boston where they were exposed to the toxic emissions from politicians up there and --

(Laughter.)

DR. KNORR: -- and brought that risk with them, and they were diagnosed on the cape, and so it made the rates look artificially high.

And thirdly, if we found that the residential history study found that the rates were elevated in the long-term residents, then we would propose a case control study.

Before I jump into this, I should just say that with the occupational study we didn't go forward with that -- the Army personnel was working with -- back in the early years -- the determination was that it wasn't possible to assemble a cohort,

so we haven't pursued that any further.

The residential history study did show that the rates were elevated in the long-term residents, so we weren't able to dismiss the elevated rates due to that factor, so we proceeded with doing a case control study.

This is a case control study that we contracted Boston University to do. They had about 2,000 subjects, looked at nine different cancer types, started in 1988, finished in 1991, cost about 500,000 dollars for the state.

And they looked at a lot of on-base and off-base environmental -- potential environmental exposures.

And at the time, people were really concerned about the drinking water because the PLUMES -- however, that was one of the most clearest findings -- is there was no association with drinking water.

They did find some associations with brain cancer and various factors that are listed here including living in close proximity to the runways at the air base on the military reservation.

And lung cancer was found to be associated to living near the gun positions where the excess propellant was burned, and all these -- I mean, brain cancer is very rare, certainly didn't account for the elevations on the cape. Lung cancer -- just a small number of cases were actually characterized as exposed.

And so overall they found -- they concluded that no more than a small part of the cancer increase that we were observing could be explained by the environmental factors investigated.

One of the factors they did look at was PAVE/PAWS back then. We asked them to do that, and they tried to make use of the measurements surveys that Colonel Ashworth had shown you a few minutes ago, tried to make use of it in different ways than an epidemiologic study.

Kreeging (ph) was one of those methods, and when they applied those, they did conclude that it was a nonsignificant decrease in risk associated with increase in -- decrease in risk with increase in power density.

I don't know if it was because of that, but they decided, "Well, there's probably something wrong with the study," so -- and their measurements were a very small number of measurements, as you recall from Colonel Ashworth's data.

So the BU investigators thought additional power measurements were recommended.

The years after 1991 when BU released their results -- as you can imagine, the community wasn't really satisfied because they weren't getting the questions answered that they had, which is understandable and so the department, during the next few years, proceeded to update cancer statistics so we could get a better idea of what the rates were.

And we decided to start looking at them by geo-coding; we had more -- an improved computer technology. We geo-coded all the cancer cases on the cape for 25 different categories of cancer -- for all the years of data we had available from 1982 on -- the last year we did it was '95.

We did it on the census-track level for public reports, and that was for this -- the five towns as divided into 21 census tracks, so it's a lot of data.

It was very controversial to even do that. It sounds like it would normally be straightforward to do SIR's for that, but it was controversial because we didn't always have inner-censial (ph) population data, so what data we estimated was the population -- for a high-growth area, was brought into question when people weren't seeing the results they liked to see or wanted to see.

So we didn't really get anywhere, and this is one of the things that we weren't really enthusiastic about doing anyway because we thought we already knew that there were elevations; we knew where the elevations were, but it prolonged kind of the agony and put more gray hairs on my head.

One of the things that came out of -- through a cooperative agreement with ATSTR that came about in 1996, I guess, was that ATSTR hired some consultants from -- technical experts from Harvard University and Clark University to take a look at the statistics that we had done -- those standardized

instruments ratios by census track -- to try to see if they can improve on them and find how to use them to identify hot spots, try to understand where the problems really lie and maybe that would tell us whether it was related to the base or not.

So this is an example of one of them. Lung cancer was really, we noticed, very high for females, and you can see these are by census track and some other areas out into Plymouth, on the other side of the canal, which is right here, so this is the dividing time for the cape, but we included this area in the study.

And then I think -- I think it's right here is the Barnstable, somewhere around there, and so this is another part of the cape over there.

We just wanted to expand out in the study area to see if we saw the pattern of elevation continuing on either end.

You can see all this dark blue -- it's all elevated -- almost all the tracks are elevated for female lung cancer.

And these are the same findings that we saw without doing any of the smoothing effort.

And this next slide just shows males just in comparison that we don't see any problem with the males. So something is going on with the females.

Some things came as a result of that effort, and one was for the state, outside of the cooperative agreement, to

do a study of lung cancer, and so we're just in the planning stages now, but I just wanted to show this to give you an idea of some of the level of effort we're trying to include.

And this is trace surface concentrations; this is to identify the meteorological fields to take into consideration the seabreeze effect and so forth that's going on there so that we could accurately estimate exposure of the population given the local meteorology in this area.

And so we've got lots of scenarios like this that are already included in our database that we'll be using when we predict and estimate the dispersion of pollutants from -- in this case, the power plant; in other cases, it will be the small groundlevel sources on the base, the jets' exhaust which is an issue, the fire training issues, the propellant bag areas, and so forth.

Back to the cooperative agreement, one of the things -- and this is a little interesting to give you some impression of the feeling for the communities' perspective -- this was done about five years ago on 1,800 surveys that we sent in on the cape, and you can see from this that most -- a large proportion of the population surveyed believe that there was a cancer problem, that the cancer problem was related to the environment.

And comparison to surveys like this we've done elsewhere in the state, we didn't see the numbers to be quite as

high; it's more -- this is more a reflection, I think, of the aggressiveness of the activists and the attention that they're getting in the media to make people believe that this is what's going on, and the rest of us haven't been able to get our message out which includes the results of the BU study showing that we didn't find an association with the environment.

And as a result of a lot of these efforts, PAVE/PAWS did remain as one of the factors people had raised that we didn't have an answer to. What role was PAVE/PAWS playing?

The department didn't have any money to really look at PAVE/PAWS ourselves until 1998 when we found a little extra money to pull together an expert panel, and we had to do this because ATSCR said that they could not look at PAVE/PAWS as part of the cooperative agreement since it wasn't consistent with their legal authority under CERCLA.

So we did pull this expert panel together, and their charge is similar to the charge that Colonel Ruscio even proposed to this group and to the NRC and just trying to understand do we have sufficient data to reach some conclusions, and if not, how do we get the additional data that's necessary.

And Dr. Erdreich who will be presenting shortly was actually the chair of this committee.

Other members was (sic) Dr. Henry Lee, University of Washington; Marvin Ziskin, who's Temple University Medical Center; and Owen Ghandi from the University of Utah.

And one of the things that's interesting to point out and Colonel Ashworth mentioned this, too, is that the committee had concluded that the potential effects from pulsed waves may be different from those of non-pulsed waves, so we need to take that into consideration in trying to evaluate PAVE/PAWS.

However, given the data that was out there and the literature now, that we wouldn't have expected to see harmful effects from PAVE/PAWS' facility.

They made a couple of recommendations. One was to limit exposures to those considered safe by national standards, those that Colonel Ashworth mentioned.

Until there was good characterization of the ARFAR exposure and better scientific evidence on basically what was important about pulsed waves -- and they specifically recommended for additional power density measurements.

So after that study, the department had some trust issues that it had to deal with because there was a conflict of issue -- potential conflict-of-interest issue raised with one of the panel members, and so people didn't want to listen to what we had to say.

So we worked with Colonel Ruscio and the Air Force to try to still have this issue addressed, and it's clear to us that Colonel Ruscio and the Air Force were committed to having a response to the community on this issue about the role of PAVE/PAWS, and they subsequently worked out an arrangement with

the formation of the steering group, which is where we're at right now.

And what I just want to talk to you about briefly is kind of where we are right now with the department's issue -- is we do feel that it's important to characterize the exposure with additional field measurements and also modeling.

We initially weren't enthusiastic about doing an epidemiologic study at this time. We felt we needed to find out what people were exposed to and, if they weren't exposed to anything that we would be concerned about, then we wouldn't need to go forward with an epidemiologic study.

I'm not sure we can do that now. There's just a lot of momentum that's already built up in the community -- to expect an epidemiologic study -- at least using existing health data, so that's what we would support.

And also it's been complicated by -- as Dr. Ruscio mentioned -- Dr. Albanese has hypothesized some other exposure parameters and health issues that we hadn't considered before and need to see how we can best address those.

These are laid out here -- and one had to do with -- as Colonel Ruscio mentioned, we want to look at biologically plausible outcomes, but what actually are they?

Different researchers have hypothesized, some based upon tissue effects and laboratory studies, and our difficulty is trying to understand whether those should be

considered in an epidemiologic study or not.

And similarly, with the exposure parameters, a lot of people, as you've heard me say, with Boston University and our own expert panel recommending additional power density measurements, average and peak, but there have been other parameters also mentioned, and how should they be considered in an epidemiologic study or even just an exposure assessment study.

Now, from the community's perspective, they do need to have this answer about the role that PAVE/PAWS plays on the cape.

They still see these health problems, so we need to provide some answer to them about that.

One of the main concerns that they have is that the process that's in place now kind of leaves them out a little bit.

There's concern that, no matter what studies are done by the Air Force, no matter how well intentioned they may be, that they're not viewed as independent and so would -- may perhaps not be believed.

I'll finally just leave you with this. This is actually recent newspaper headlines. The first one is actually laid out by -- a question laid out by the paper and inviting people to respond to, and these are some of the subheadlines from individuals who wrote in.

They illustrate some of the points we've been

talking about so far about the need to have health information included in a study in order to understand the role, how the issue of trust and independence of this effort is an important factor.

The classified studies -- is there something that the military knows about what the health effect of the pulsed waves might be that nobody else knows about, and so, when we design a study, it'll be flawed from the start because there's information not available to the planners of the study -- that type of thing.

So I thank you for the opportunity to talk and be happy to answer any questions you might have.

DR. OSTROFF: Thank you very much. Let me start by asking a couple of questions. This is obviously a very complicated situation, and you have multiple facilities, for want of a better term, that conceivably could be linked to some of these problems.

I don't know any of the details of what was done in the case control study or any of the other studies that have been conducted.

I can imagine it must be very difficult to try to separate out exposures to one of these facilities from exposures to one of these other facilities; however, it strikes me that, if -- you know, some of the concerns are, as a superfund site, it dates back to World War I, and then this facility was built in

1979. You presented data about cancer rates after 1979.

I would assume that you have at least some data about what cancer rates were like prior to the time that this facility was actually built.

DR. KNORR: The only thing we have is mortality data, and I don't recall offhand whether it was elevated or not, but we haven't focused a lot on the mortality data because of its limitations.

(Pause.)

DR. OSTROFF: Yeah.

DR. SHANAHAN: Dennis Shanahan. How confident are you on the elevated FIR rates?

DR. KNORR: I think it's been -- it's been reviewed by a lot of people outside the health department, and I think we're very confident that they're real.

DR. SHANAHAN: And these studies did control for length of exposure, that area.

DR. KNORR: Well, the SR's that were done would not have done that, but that issue -- in the BU case control study and our own residential history study -- and they both independently tried to address the question about this risk that we're seeing -- is it that we see elevation in the long-term residents, and the answer was yes, it's the long-term residents that this risk resides in.

DR. SHANAHAN: Okay, thank you.

DR. OSTROFF: Bill?

DR. BERG: Bill Berg. One of your slides -- one of the conclusions of the PAVE/PAWS expert panel -- no definitive scientific evidence, however, that the anticipated low RFR levels could cause any harmful effect.

Does that mean that the panel said, even if you measured and allowed for the pulsed array, that we still don't think anything will be found?

DR. KNORR: Well, that might be a good question for Dr. Erdreich later, but it's my recollection -- is that the issue that -- the issue that -- issues that Dr. Albanese, for example, is bringing up, that it had to do with various characteristics of this pulsed wave weren't discussed at that time.

But as I mentioned earlier in the slide, that there was a conclusion of the panel that, because we were talking about pulsed waves, that perhaps they know the pulsed waves probably have a different effect -- the non-pulsed waves -- so that that needs to be taken into consideration, but whether that conclusion is based upon that observation or not, I'm not positive, and Dr. Erdreich might be able to clear that up.

DR. BERG: And that's what I was getting at because the previous bullet says pulsed waves may have a different effect, and I was trying to figure out -- there's a bullet right after that saying, "But even if it does, we don't

think it makes any difference."

DR. OSTROFF: Let me ask another question, and that is, while you're focusing on the long-term residents, if this is an area in which lots of people are migrating to, is there some sort of way to look at a dose effect phenomenon -- i.e., those people that are moving to this area -- do then they acquire a higher risk over time of also being at higher risk for some of these adverse health events?

DR. KNORR: Well, if I'm understanding the question -- to me, maybe that's an issue of whether exposure has a cumulative effect or not. I think that was discussed by our expert panel and Dr. Erdreich can talk about that as well, but in a study of chemical exposure, for example -- I mean, that's what we do -- when we look at ionizing radiation, that's what we try to do is take into consideration the length of residence and weight it according -- you know, weight their exposure to -- according to their length of residence, for example, that type of thing.

Ideally, it would be good to do that, and in the kind of epistudy that we're talking about in the steering group right now, it wouldn't be collecting that type of information. It would only look at existing data. It would only tell us where they lived at the time they were diagnosed, and we wouldn't know how long they lived there.

So that's a limitation of that.

DR. OSTROFF: What's your potential -- I mean, is there a potential hypothesis about why this would differentially affect women versus men?

DR. KNORR: For lung cancer, we have some hypotheses that there's some genetic components in women that are felt to perhaps put them at higher risk to environmental exposure -- smoking or nonsmoking exposures, and allow them to show -- display cancer as an outcome more so than the male. That's one hypothesis that's out there.

MR. FRIEDL: Friedl, MRMC. We know a lot about exposure around power lines, but this is a completely different frequency, and all the characteristics are really quite different. Do we have anything else like this that's been studied before?

You know, we have a tri-service RFR research group, and they're always kind of on the ropes. Every year we've got to say, are we going to continue to fund this because everyone says, "These aren't important issues." And it looks like there are important issues here, and this is an area that -- you know, we're looking at things like risk for Parkinson's Disease. Well, that has a pretty long latency.

You're only at 20 years out here; maybe it's going to be 30 years before you see any connection.

So what do we know about this particular sort of frequency range?

DR. KNORR: I think, again, I'm going to let Dr. Erdreich talk about that because that's really her topic for discussions -- the epidemiology of these types of waves.

I know that, just speaking myself, there's interest out there -- I've gotten calls from California related to Beale and people wanting to do a study.

I got calls from Israel -- I think there's a facility being built or is built there, similar, where they're interested in having a study done.

I don't know of any studies myself -- certainly no human epidemiologic studies that I'm aware of.

DR. OSTROFF: Dr. Malmud?

MR. FRIEDL: Guinea pigs exactly the word they used. They should hire you out.

DR. MALMUD: Malmud, Temple University. There is a group at Temple University which is studying the effects of low-level electromagnetic waves on biologic systems.

You mentioned one of the investigators earlier, Dr. Ziskin, who's part of that group, and they are actually looking at intensities even lower than the ones mentioned here -- so low, in fact, that we had to build the facility at considerable expense which totally shields the experiments themselves from all other waves which -- because the background is higher than the wavelengths -- than the energies that we're measuring.

Interestingly, about 40 years ago, Herman Schwan at the Moore School of Electrical Engineering at the University of Pennsylvania was looking at the effects of low-level magnetic -- electromagnetic waves on biologic systems.

But at that time, Dr. Schwan, who was one of the early investigators in this area, did not have some of the electronic methodology available -- it had not been developed as yet -- to measure the impact of low-level electromagnetic waves and whether or not the effects of these waves, if any, were due to the wave itself or to the heat generated by the wave.

A group at Temple is now able to separate out the two effects.

So Ziskin's initial studies have not shown in small biologic systems -- snails, mice, rats -- any effect of low-level electromagnetic waves, and in a preliminary abstract, which I believe has been published, has been able to demonstrate a salutary effect but certainly not a damaging effect.

Dr. Ziskin and his group may represent a resource if that's what's being sought, but they are not doing studies in patients looking for negative effects.

(Pause.)

DR. OSTROFF: Any other questions or comments?

(No audible response.)

DR. OSTROFF: Why don't we move on to the next presentation. Thank you again so much -- I'm not sure -- Dr. --

DR. OSEPCHUK: Osepchuk.

DR. OSTROFF: -- who is the former president of the IEEE -- I guess that's how you would say it -- the Institute of Electrical and Electronics Engineers. He's going to discuss the exposure standard issue.

DR. OSEPCHUK: My name is John Osepchuk. I'm the past chairman of the IEEE committee he referred to, what is called the international committee on electromagnetic safety now, and it's described in the second page of my handout.

I'm going to refer to the handout for answers to any detailed questions because much of it is really not controversial, but I feel you have to have it on the record.

As chairman of this committee -- by the way, I want to compliment you epidemiologists for your spartan-like schedules, meeting at 7:30 in the morning. The groups I chair complain if we meet at 8:00.

(Laughter.)

DR. OSTROFF: Only because it's the military.

DR. OSEPCHUK: I also wanted to give tribute to the military and particularly the Air Force.

I've been in this business since 1968, and I can assure you, if you want a detailed history of that -- the presence of rational standards in this country and in the world, really, in large measure are due to the support of the military in supporting these standards organizations, particularly the

IEEE.

The military is -- Brooks Air Force Base -- they have all services, and perhaps the biggest research laboratory in the world on this subject.

And the gentleman from Temple University mentioned Dr. Ziskin. Dr. Ziskin and Professor Schwan are both members of our committee and strong supporters of what we do, and I believe join in the consensus that I'll express in a second.

In terms of full disclosure, I want to say something about my background. It's relevant in various ways -- as I go through here quickly.

First of all, I was educated at Harvard after World War II, and during those years I had the privilege of listening to a visiting lecturer named Leon Brillouin who was a famous physicist cited in many of the works that people will bring up. He was a brilliant man. I read his book, and I cite that only to the fact that I know something about what he meant by precursors.

I worked at Raytheon Company for 40-plus years, and in 1979 I helped the U.S. Attorney in defending the Air Force in PAVE/PAWS in federal court in Boston.

However, more important than my help, perhaps, was the work of Raytheon engineers in answering a favor from Judge Tauro who wanted to see what the fields were in his courtroom.

Well, his courtroom at that time was in a high-

level floor of the federal court building with a beautiful view of Logan Airport.

The results showed that microwave levels from Logan Airport far exceeded whatever was being measured on the ground from PAVE/PAWS. Now, I'm not sure that that greatly influenced the decision, but certainly I think he was greatly interested in knowing that.

(Laughter.)

DR. OSEPCHUK: My wife's family has had a home -- a second home in Cape Cod for many years in Barnstable, and therefore I have personally been involved in many of the things that people cite about the activist activities and so forth, and I have had personal reasons for going down there and making surveys and so forth.

The question before you is about whether or not an epi study for PAVE/PAWS is worthwhile.

As I see it, the only proper reason is not biological data, not even engineering data but the speculation of one scientist, Dr. Albanese, about the very novel hypothesis that high levels of dE/dt -- and I apologize to you epidemiologists if you're not physicists or engineers -- but I failed -- it's unavoidable to address this hypothesis, since that's the only really proper reason for doing this -- there's nothing special about the environment in PAVE/PAWS or Cape Cod. As a matter of fact, it's law.

But if PAVE/PAWS had some type of special signature like a DNA signature or something that made it particularly dangerous, well, then maybe you should do it.

But as you'll see, many of us -- at least most of us believe that his reasoning is flawed, and I want to give you some idea about how it is flawed.

This is the first page of my outline. What I plan to do is just put up a couple of slides indicating that the levels that are measured indicate that the levels anywhere in Cape Cod from PAVE/PAWS are well below standards of the world and well below many other things in the environment.

Then I'm going to spend most of my time on addressing, if I can, what I understand this hypothesis to show -- that it really -- I use the word "reductio ad absurdum" -- leads to conclusions that are not acceptable and therefore needs to be rejected.

As a face-saving gesture, I point out that his emphasis on waveform may have something new to contribute, but it doesn't relate to PAVE/PAWS; it relates to what I call hot spots in the environment.

In terms of standards around the world, Dr. Ruscio mentioned that it's important to mention microwatt per centimeter squared. By the way, I mention in my handout that the epidemiological study at BU by Arshengrow and Osanoff (ph) had a typo, and epidemiologists should be very careful -- they put in

an "M" instead of a "micro" and therefore overstated the power density by a factor of 1,000.

So epidemiologists should be careful in using prefixes.

(Laughter.)

DR. OSEPCHUK: In any case, here's the -- our standing -- and here is what's called ICNIRP, very similar.

The British actually have a much higher level as a group -- a substantial group in the IEEE group -- ICES group that wants to raise this.

Surprisingly, the Communist countries have always had a much lower thing, and people say they must know something we don't.

But, believe it or not, that is starting to crack, although it's difficult to raise something.

The Czech Republic did, in fact, change from 10 to ICNIRP and I just got recent words that the Chinese are going halfway.

So the trend is not that things are getting tighter, but everything is converging in this frequency range to basically what we have in the IEEE standard.

And, therefore, there's very little likelihood in the near future that anything in the standards world is going to say, "Aha, now PAVE/PAWS is dangerous."

The other side of the coin is -- and I just take

this one slide from the studies of Mantaclay (ph) who with TEL (ph) have done most of the surveying in this country.

This is a busy slide, but you've got it in the handout; you can look at it, and if you look at the reference to the Biomagnetics Journal, you can find out that all kinds of things in the environment have been surveyed.

He puts it on one master chart the range of fields that he sees in the different frequency ranges like TV and so forth.

And you can see by comparison that PAVE/PAWS -- these are the maximum peak levels and the maximum average levels -- PAVE/PAWS is really a small pot of the electromagnetic environment -- if you look at it as a whole -- and later I'll mention a couple of anecdotes that also indicate this.

Now, to -- let's see -- what's the next slide after that?

(Pause.)

DR. OSEPCHUK: Yeah, that one there. Save that one there, but this one here -- I want to tackle the hypothesis of Albanese.

This is well produced from a study by Stoudt in 1995 or '6, and basically everything that Albanese has done is with very short pulses -- really, ultra-wide band pulses -- and by the way, the PAVE/PAWS sequence are not ultra-wide band

pulses. I don't have time to go into the detail of what that'll do.

And what he finds -- and I first heard in 1987 -- you have a pulse like that, and he sends it into material like water which is a -- has a frequency -- attenuation that's highly frequency sensitive so that, you know, a change of frequency by a factor of 10, the attenuation goes up by a factor of 10.

And in a few centimeters, lo and behold, instead of this, he gets this.

And this later on in later years -- he started to use the word "precursor" which is not valid but is a minor part of the story -- but what he failed to recognize and even to this day maybe is the explanation by Stoudt is that you see -- this is counter-intuitive, but a short pulse like that has a very broad frequency spectrum; that's why it's called an ultra-wide band pulse.

By the way, the PAVE/PAWS pulse is not really that short.

And because of these low-frequency components, you have to look at the amplitude.

What really is happening is, because it has such a broad spectrum, this part of the spectrum way down here doesn't get attenuated because of the low frequencies, and therefore what came through is the low-frequency part of the pulse.

(Pause.)

DR. OSEPCHUK: This is from Professor Stratton's book in 1941 in which he quotes Brillouin's work, and precursor really is for any material -- in those days, they weren't talking about water; they were talking about materials like Teflon or some dielectric material.

And if the signal went at the speed of light, you would arrive at this time at this distance, but in fact it arrives here because it's slowed down, and in this little period before the pulse arrives, you get these very weak -- very, very, very weak -- what are called precursors.

Now, I just think of a digression for a second -- to point out that the explanation by Albanese is not quite the same as what -- Brillouin and Stratton.

Albanese looks from -- a quote from his recent article in the Cape Cod Times:

"Our work thus defines a steep wavefront as one that is close to or exceeds one volt per meter per nanosecond."

And he says, you know, this curious statement -- there are things that are happening. He says, quote,

"In a sense, the electro-magnetic signal is coming in faster than the tissue can handle."

Say that again.

> "In a sense, the electro-magnetic signal is coming in faster than the tissue can handle."

In other words, can react to it.

That really is flawed physical reasoning as compressed -- for example, take from Stratton, 1941, his description of what happens when a wave coming from Brillouin and Sommerfeld --

> "Qualitatively, at least, we can imagine a medium as a reason to freeze-spray... intensely infested with electrons, an infinitesimal amount of energy penetrates the empty spaces as through a sieve traveling, of course, with the velocity of light [that's the precursor]. Each successive layer of charges is excited into oscillation by the primary wave... energy both forward and backward. By reason of the inertia of the charges, these secondary oscillations lag... [and so forth and so on] and that results in

reduced velocity. This picture indicates that the medium reacts quickly and stops the wave immediately until these things cause slowing waves."

So the bottom picture is -- from my viewpoint and I think most of my colleagues' -- Dr. Albanese has a flawed physical picture.

But let's go on to the next slide where I hope to show that this leads to one acceptable conclusion.

(Pause.)

DR. OSEPCHUK: First of all, just to make a simple calculation -- I don't think you have to be very brilliant -- take a sine wave and differentiate it; you have E and the dE/dt and you really see that the two go along together.

But then, if you just take a sine wave and make calculations -- at what level of power density do you have a dE/dt in the way that exceeds this one volt per nanometer per one volt per meter per nanosecond -- you get some amazingly small levels.

Now, of course, this is in the wave, but Dr. Albanese says, if you turn it on, turn it off or change -- for example, you go from one power cycle to a high cycle and a change is this amount -- it's trouble, okay?

The implications lead to the following if this is correct -- if this were correct. It would lead to the

conclusion -- yeah, go on to the next slide. Down here it says you can show that -- if this is correct, you take a laser frequency of a visible range -- and amplitude-modulate it at one gigahertz, which is being done today -- this is called optical communication.

If you can show -- and I have shown on paper -- that you would violate the Albanese criterion at some enormously low level -- minus five or something -- might go up a centimeter squared -- and that's absurd -- and if it were true, you should shut down immediately optical communications because that criterion is being violated.

Furthermore, and I guess maybe in the previous slide I didn't mention that if you -- Dr. Adair has done this and I've done this -- because PAVE/PAWS mentions dipoles and the rate antennas -- those antennas don't radiate the hold -- they only radiate around 500 megahertz, and the frequency ten times lower -- they radiate 100 -- the efficiency there that the 500 megahertz -- you can't radiate a baseband signal from those antennas.

And for that reason and for other reasons, it's very unlikely to measure any steep wavefronts from the PAVE/PAWS radiation.

Finally -- so you're going to find no particular signature that's exciting.

However, there's one saving grace from my

viewpoint about what Dr. Albanese has done. He's pointed attention to the waveforms.

What's of interest in the waveforms? It's true that waveforms have not been studied, and maybe someday it'll be important.

I took a Godanken experiment of 23 frequencies mentioned here and put them together, and what you can show -- that's part of your handout -- but I -- wait a minute -- this is my conclusion slide indicating that what you'll see in a second -- if you have these 23 frequencies in a hot area, you can get some high peaks by beating wave phenomena.

And it's very interesting to study. It might take 10 to 100 million dollars, but it's only based upon my speculation that's interesting. But that's real as compared to looking for dE/dt which I think is not very rational.

Oh, a preliminary slide -- I'm going to mention the hot spots in a minute. Hot spot is a place where your power density might go up a centimeter squared. That's a crucial point of the -- Dr. Ashworth pointed out the levels at Cape Cod are typically below .06 -- that's close to the site -- and power wave drops out to very small.

In Newton, Massachusetts, the hot spot where we have many signals -- and the power density is about one microwatt per centimeter squared, and if you walk around those towns, this device called a microalert will chirp. By the way, you notice

it's slightly chirping here.

What does this device do? I have a children's walkie-talkie. I turn it on. Then within six inches, it chirps.

So this is detecting a level of flux from a children's walkie-talkie within six inches. It's not a terrible amount of energy, but it gives you an idea of perspective.

In Cape Cod, with this device, the spectrum are (sic) much, much greater, and if you go all the way around Cape Cod, you will not get a hot spot.

In Newton, you will, and if you take 23 signals -- this is a Godanken experiment -- you can get peaks that occur periodically that may be 23 times higher than one signal in e, meaning 400 times effective power nets (ph) -- these are some little -- an exotic subject, but if there is some interest in using waveforms, it should be in hot spots like that of Newton.

And, finally, mentioning hot spots, I use this device going around the country to indicate where there may be significant levels.

Airports are very hot. I picked up a cluster of people in a certain road where it passed by frequently -- there have been a couple of mysteries like the hotel in Coral Gables where the floors between the third floor and the seventh floor were chirping.

The Doubletree Hotel in Arlington, Virginia -- I invite you to go there -- it chirps all over the place.

Lastly, I went to the beach here -- this is a hot area -- walk out on the beach; it chirps continuously. Out in the parking lot, it chirps continuously. This is a hot area.

Now, where is the energy coming from? One of the problems is that we have a terrible inventory of sources, and some of these cases that I've mentioned, I go to my friends in the FCC and NTA -- "Tell me what transmitters are out so I can explain what I've measured," and they don't give me the right answers. They're not -- they're either not telling me or the inventory's pretty bad.

So my bottom line is that you really have to worry about hot spots, maybe starting with this beautiful site here. Thank you.

DR. OSTROFF: Thank you very much. We have one more presentation, and we're running a little bit behind, so why don't we defer questions and have Dr. Erdreich wrap up the presentation so that we can have a few minutes of discussion.

MR. FRIEDL: Is it true that there's going to be a test on this material?

(Laughter.)

DR. OSTROFF: We're going to chirp.

DR. ERDREICH: I just -- from sitting over there, it was rather bright. If anyone thinks it would help them see to close the curtains, you know, I'm not in charge of curtains, but -- just a comment.

I'm delighted to be here. I really enjoyed this morning's presentations. This is all new to me. So I thank you for the invitation, and all I can promise you is I'm going to truncate my talk because you have the handout, and I am going to talk about epidemiology. Engineers don't like it.

This is to give you a perspective, and I think I probably overestimated the PAVE/PAWS radar because I used like the highest exposure anywhere outside of the base.

But I wanted -- this is just to give you a perspective, and it does have a relationship to the epidemiology studies.

Basically, that shows you that the exposures from PAVE/PAWS maximum in the community are more than you would get from a cellular antenna base station, maximum in the community -- don't even think about cell phones.

What I want -- I was asked to review the epidemiologic data. There's lots and lots of data of varying quality, and part of the reason it's of varying quality is some of it goes back many, many years, and people had fewer resources.

But I am taking a risk assessment approach -- that is, how do you assess human health risk? But I'm speaking about the epidemiology.

There is -- risk assessment's a very common thread. We happen to have written a risk assessment paper.

The next slide lists the areas where you can find

data on epidemiologically -- whoa -- you know what I mean -- epidemiology studies of human health and radio frequency exposure are available for a lot of different endpoints.

Now, up in Cape Cod, cancer is the big one. I'm going to speak most about that today. I'm going to talk about reproductive endpoints for two reasons: pregnancy outcomes and male reproduction have studies that report some positive associations, although the studies have some flaws.

Thermophysiology is the -- there's huge literature on that; it's not necessarily epidemiology. There are studies of general health endpoints.

Now, in the next column there are studies related to radio frequency, but they have been sort of forced and encouraged by cell phone issues.

So I'm going to stick mostly to cancer and reproductive outcomes -- mostly cancer.

This is standard operating procedure. It's just my way of saying, "Look, I'm not going to tell you about every study 'cause every study doesn't provide information." Some of them are screening studies; they've been -- job titles only, proportional mortality, and they've been superseded by better studies.

So what I wanted to do is just give you kind of a quick overview of the studies that I consider informative. Whether they're positive or negative, their quality is such that

they provide information.

They have acceptable study design, standard operating procedure -- large sample size. They describe individual exposure.

One of the things that I had to do a little differently than usual when I do, say, a human health risk assessment is sometimes there are studies where the exposure is minuscule, way below the standard, way below what could be -- by conventional science -- not a few studies -- known to expect living things.

But since we're talking about PAVE/PAWS where the exposures are also very low, I'm not going to throw them out. I'm going to, you know, put them in the list.

The next slide -- just kind of my justification for studies I haven't included -- there are -- there are two studies that have incredibly biased and unclear study designs.

If you were reviewing them, you would easily identify it. Only the public will take the results of those studies and wave them around and scream about them, unfortunately.

There are studies that are small sample size, low response rate and so on, and admittedly this slide is in there to explain why I'm not including the studies.

The next two slides are just an overview of the exposure assessment in the studies. I mean, basically, in the

handout you can see the exposure assessment and the sample size -- some but not all of the relevant criteria for asking what do these studies tell us.

The radar lab studies -- an interesting study because it's unpublished -- it's a Hopkins dissertation, and Dr. Hill just never saw fit to publish it. I guess she thought 'cause it was negative it wouldn't be important. Oh, my.

She used -- this was the researchers in the MIT radar lab -- which includes work history, job -- you know, real job exposure matrix, and the exposures were by standards supposedly conforming to the standard, but we're talking in a range that was stronger than most other studies, and the follow-up was long term. I mean, they waited till 30 years later to assess these people.

So it's a small size, but that's an interesting acceptable study design.

The study by Lilienfeld of Forest Service workers was prompted for political reasons, and it did a very good job of ascertaining people for cancer studies, but they were spread all over the place. The exposure was minuscule, and these measurements of minuscule levels were taken at places where people don't always hang out in, like around the window.

Robinette's study of naval personnel is interesting. He used both job title and he justified why he used that job title to just take -- you know, make an order

of -- order of exposure, and he used power rating of shifted -- to -- of saying make a hazard index.

There's a little flaw in the way he uses an exposure assessment group which detracts from the results of this study.

What's most interesting about this is a couple years ago -- this was Korean War veterans, published a couple decades later, and I understand that they were working on an update, which would be very useful, but I haven't heard anything in a long time.

These three are interesting. The amateur radio operators -- he used a list and found increased leukemia, but he used a list of licensed operators.

There's no doubt in my mind that those amateur radio operators may be exposed.

Of course, my husband has held a license for as long as I've been married to him, which in his definition is forever -- I've never once seen him use any ham radio. I've heard him talk about it, but he's never used it.

The Motorola workers is the one study that -- like a modern job exposure matrix, cohort study -- I will later go into its flaws, strengths and limitations -- that was done recently. I do have to confess, it was done by the company I work for but before I joined.

The Norwegian electrical workers was -- the jobs

there -- this was a record linkage study, and this one found a positive association, so it's important to think about how it was designed.

It judged several jobs as being capable of having radio frequency exposure.

If you look at my review of the motor workers, you'll see the problems with that kind of assumption.

Three quick summaries of -- this is the overview. The Hill study had a long follow-up, you see, but it had a small cohort size, didn't find any important associations.

I put all cancer and leukemia just because those are the things that have been discussed -- that and brain cancer has been discussed.

Several of the older studies lumped hematopoietic and lymphoproliferative diseases -- hem and lymph -- they were often reported -- I didn't include them. I'm not admitting anything ragingly positive.

The Lilien study -- you can see the wide confidence interval. It was based on a very small number.

The Milham study is -- has -- he points it out as positive.

The Morgan study is the one that was done by -- in the Motorola workers, and that was consistently negative -- huge sample size, but some limitations.

And the Tynes study, that Norwegian study -- see

how it reported a statistical association that only looked at leukemia and brain cancer.

But their assumption was I think they -- this kind of job, yeah, they could be exposed.

Now, using that definition, a huge proportion of Motorola workers would be exposed. Let's go and look at the Motorola workers.

That was a large study. Goody, goody, goody, 195,000 people lots of person-years, not that long a service or that long a follow-up, but at least we know how much it is. The exposure assessment, only a small proportion had moderate or high exposure, however, based on their definition. Still, supposedly things were supposed to be below the standard.

They looked at exposure three different ways: cumulative exposure, longest job and peak exposure. They did this because, except for the thermal mechanism, which would say we don't need to do this study, they don't know any plausible mechanism for long-term low-level exposure. This study reported both SMR and an internal comparison. These were very middle-class workers, big, healthy worker effect.

The Motorola study was very consistently negative, but -- turn to the next slide, please -- very wide confidence intervals. They're a little narrow when they do the internal cohort, which -- I feel it's very important to do the internal cohort because this was such a healthy population. This just

shows you. Not positive but very wide confidence intervals.

The Motorola study, the Morgan et. al., which is -- certainly follows all the rules of a good cohort study -- has limitations in the exposure assessment because they really didn't measure anything in time. They did have a relatively small proportion of highly exposed workers, and the cohort was somewhat young. However, they did have 29,000 people over age 60. The latency periods would be inadequate for some of the cancers. So there were some limitations as well as the strength of the numbers.

The cell phone issues -- these are three crise (ph) control cell phone studies and one cohort study. They only looked at brain cancer. There's certainly insufficient latency time based on what we know about cancer. So these studies, which are certainly not positive and fairly reasonable design, certainly tell us that we're not finding any unexpected promotion effects or unusual effects in this time frame, which doesn't cover latency in a proportion of the cases.

Male reproductive function. I kept thinking about these studies -- this and pregnancy outcome as you were talking about your RAP program because these are studies that could use more data. They're not necessarily long-term. It looks like some day the armed forces might be in a great position to do some really good studies on this topic.

Semen parameters and hormone levels as a test of

male reproductive function were studies by Schrader with a group of people in 1996. He took his control group from -- he was studying lead and he used military intelligence workers for his control group and someone said, "Oops, maybe you shouldn't do that because they're exposed to radio frequency. We have concerns. We don't know." So we did it again, did a study keeping that in mind. So we had three groups exposed and two different control groups. He didn't find anything that would indicate a male reproductive effect. These were a huge number of semen parameters and hormone parameters.

In the Grajewski study, the next one, they found minor differences from control and a few of the 37 parameters in heat sealer operators. Two important points here: Heat sealer operators are on the verge of being exposed above the standard; although, based on foot currents, they weren't.

The other question there was the study was small. She reports something positive not with -- outside of the normal range, high FSH levels but not different from the other group, statistically significant but not out of the normal range.

What she says is important for, I think, all of these -- the reproductive studies. "Well, it was negative, but we don't feel comfortable at being strongly negative because the sample size was too small."

So you have a lot of this, well, it doesn't rule it out. We didn't find anything, but it's not of sufficient

power to rule it out.

For these things and for the next one, cancer, male and female reproductive effects, if you look at the animal studies, they are fairly complete. They're thorough. There's quite a number of cancer studies. You could possibly design some additional ones, but the animals do not get cancer. As long as you keep the radio frequency energy below the level that would increase heating, that is essentially below what we use for the standard, the animals do not have diverse effects. They live. They have babies. They have generations. They have babies. They're healthy, no birth defects and no resorptions. I think that's an important part in the risk assessment.

There's a large number of pregnancy studies, including some from Scandinavia that are very small. People often quote them as positive, and often they are just so incredibly small that what they consider a positive association is highly unconvincing. However, there have been, since this early time, some better ones.

What still remains is that one study reports an association between miscarriage and microwaves, which is biologically puzzling because the microwaves hardly penetrate into the womb, into the uterus. So it's biologically difficult. There also was a problem with low participation level, although it was a very large, well-designed study, those two questions.

Then there's another study recently came out that

shows an association of low birth weight and a few other end points with short waves. Well, it could be biologically plausible. These exposures should have been below the standard. The studies are of physiotherapists, whose exposures may exceed recommended limits.

So my bottom line here is that what do the epidemiality (sic) studies alone -- and that's not, of course, the whole question for assessing health risks, but what do the epidemiality studies alone tell us about health? The exposed populations that we have studied do not show convincingly increased cancer or leukemia. There's reports here and there, but when you put it all together, it's not consistent or convincing.

The cell phone studies have not found increased brain cancer, and the human studies are not consistent with the idea that there may be adverse health effects at levels below standards.

However, there are still some not exactly data gaps, but there are areas that should be shored up. There are studies in progress -- this is the status of the research today, in my opinion. The studies in progress -- there are several -- are focusing on cell phone use, which is very localized exposure. A follow-up of the Motorola cohort would, I think, be very useful in filling gaps about cancer. Other exposed cohorts exist, no known studies in progress.

I think I should not have said that, because I recall that the military is -- I heard they were doing a follow-up of the Robinette study. I apologize that I didn't check that out. It just occurred to me on the plane out.

To clarify local issues up in Cape Cod, it's possible that statistical advances in small area studies and cluster assessment could be used, because that's a relatively small area to be doing cancer rates.

My last thought is that I really did a lot of -- couldn't help thinking about your recruit program when I was thinking of some of the follow-up needs. I don't know what your schedule is. I'll be available to answer questions that came up later. Thank you.

DR. OSTROFF: Thank you very much. I think we have time for one or two questions. Let me ask if there are any members that have a question.

DR. HERBOLD: Just one question. We've had one presentation with some data on the engineering and the physics aspects. Has Dr. Albanese published any information on his hypothesis that would be available for review?

DR. OSTROFF: Bruce, can you comment on that?

LT. COL. RUSCIO: Yes, sir, I can -- there are two papers that Dr. Albanese referred to, a 1994 and 1997 paper. I can provide those to you. You can determine the -- how it relates to the issue.

DR. OSTROFF: I have a question. What is your assessment of the -- I mean, this situation, which -- I mean, I must say, quite frankly, seems to me to be more of a -- I shouldn't say more of, but to a large degree, a tremendous public relations problem. I mean, there is clearly something going on in this community in terms of having some excess cancer rates. It seems to me that, for whatever reason, people have latched onto this facility as being the cause.

MS. ERDREICH: I'm not up there daily, but I've had some hard times up there. There is something in this community. There is widespread -- well, there's a widespread consensus on the standard that only worries in a little area of the quantitative part of the standard. There have been a lot of people going around, including one of the people on the expert panel group, who believe that there are levels below the current hypothesis about thermal effects. They usually present cellular studies to support their point.

Cellular studies have to be judiciously interpreted because some of them are designed to be symbolic. Some of them are well known to be predictive of cancer. Others are just studies and it doesn't tell about how this cell works when it's in the whole body, in the organism. I don't think those people know this. I think they like it when someone comes up and gives them feed for their argument.

I can give you one very frank response. When I

was looking at the resumés and the people on this board, I was thinking, look how many people on this board are involved in health promotion and communication. Quite a large number of you are.

Somehow or other this community has lost its focus on what really affects their health. Their concept of the environment -- maybe they read. Epidemiologists write things, "This is a risk factor," when it may be hypothetical because it was reported a statistical association in one study. Epidemiologists write about environmental factors, and they mean your diet and they mean your level of exercise and cigarette smoking, but the public hears "the environment" and thinks it the air and the water. So I really feel that a lot of it is communication.

Every cancer rate that's examined in the United States is not going to be one. That's statistically impossible. So your read is pretty accurate. There's something else.

MR. FRIEDL: I've got to point out that, for years we've been told the new non-thermal bioeffects are important. In the last couple years, the Brookes Group showed that, in fact, with ultra wide band, exposing rats for six minutes to a non-thermal dose, they had a drop in blood pressure of 22 over the next two weeks.

So there really was an effect there. They've reproduced that. There are some things out there. So we need to

just be open-minded about this at the same time.

I'm not saying that has any bearing on this situation. It looks like, you know, there are convincing arguments that we're so far below the range and, you know, any kind of thermal heating for sure --

MS. ERDREICH: Well, we're not even talking about -- you know, there's thermal and there's non-thermal and then there's -- magnitude below. That's the reason that I bring in the animal studies, because I think the epidemiology studies -- I would prefer to see epidemiology studies up -- I think the ones that are higher level are more informative because that's the way you test them. The fact that -- unless you measure very subtle end points, the animals that have been exposed over their lifetime do not show untoward effects. We have to look at that.

So I'm really not taking the position that there aren't any non-thermal effects, but basically that -- I think the research community is basically still trying to prove that. I think it's encouraging that these exposures are not at the standard, although cell phones are pretty close -- not half below the standard but really over 100 times below or a thousand times below in the way that, using the median level -- so it's a real challenge.

These kinds of discussions in the old days wouldn't -- where we're still studying something, wouldn't be out

there in front of the public, you see. It detract -- they feel the lack of confidence if someone goes and tells them, "Well, I did a study in my lab and I found something in these cells."

Someone else who's a cell biologist can put it -- "Well, yeah, but here's the way I'd like to replicate that study," or, "Here's what's wrong with that study." The public thinks, oh, there's something --

MR. FRIEDL: Well, a lot of this goes to bigger issues that Colonel Cropper has raised, that we're starting some initiatives on now to do some more research on risk communication. It's, you know, how we deliver the message and the impact of the message. I mean, Three Mile Island had, what -- it resulted in a sixfold increase in office visits or something. In the end it was a predicted actual hazard of maybe one increase in cancer deaths.

MS. ERDREICH: I must --

MR. FRIEDL: So, you know, in a lot of our -- the other part of this is as a result of Gulf War illness. We've been forced to do a lot of studies like it sounds like you're about to have to do here just to rule out.

MS. ERDREICH: Ruling out -- well, a full database rules out just -- I think the risk communication problem started in 1979, well before any talk about risk communication, not anybody culpable. It was a different era. People looked at things differently.

DR. OSTROFF: Well, it -- I mean, it seems to me that, you know, this is a circumstance where it's going to be, at least as far as I can tell, exceedingly difficult to prove a negative and do it in such a way that the communities in this area are going to believe any of the people that are involved either in expect scientific committees or anything else because they think that they're all biased.

You know, it strikes me, how long do we continue to do longitudinal studies in this population before anybody is going to be satisfied that there is a negative? I don't necessarily have an answer to that, but I don't think it's particularly -- at least that I can tell, particularly productive to keep on pouring efforts and resources into trying to prove a negative that nobody is going to believe.

I'm just wondering, are there -- those of you who have been working there, are there folks in the community who are supporters of this facility at all that -- and to what degree -- I mean, setting aside expert scientific panels, to what degree have you tried to get, you know, some group in the community invested in being somewhat, you know, affirmative about this facility? I mean, it does bring resources to the community.

LT. COL. RUSCIO: Yes, sir, I think I can answer that. If Dr. Knorr wants to chip in, you certainly can do that.

There are community members who are supportive of

the facility and of the Air Force. Certainly I believe we've done a gallant attempt at risk communication within that community. We focus on the 80%, the rest of the community that does read the newspaper, reads these issues, has questions in their mind about this facility, those that have not formulated opinion necessarily but actually have an honest concern and present those questions. I've been there for two and a half years.

There's a large amount of the community that I believe does support the Air Force and the facility but still have questions and concerns. Those are the individuals that we're trying to approach and have as stakeholders.

I guess the other point is there are frequently the silent individuals, the quiet ones, the ones that don't show up at meetings and raise the issue.

My one slide -- and I didn't comment on it -- in addition to the community, there's a focus on this issue from within congressional representatives, approaching the question of the wave form characterization and characterization efforts. So the Air Force is going to move forward on part of this effort. I appreciate your question as far as how long or how much further we should go on with trying to convince some individuals or parts of the community that we won't ever convince. I'd like to suggest that that's not -- those aren't the individuals that we're focused on or we're working with. It's the other part of

the community that we need to work with to try to provide an answer on these issues.

DR. OSTROFF: Yeah. Let me just say I took it as a given that there had to be some congressional interests somewhere. If I remember correctly, one of them has a compound somewhere near there. Dr. Knorr, I don't know if you want to comment on that.

DR. KNORR: Yeah, I just wanted to say that one of the reasons that the department has been moving toward urging an exposure assessment study at least is because we have had experts on the area, Boston University experts, our own expert panel say, recommend that additional field measurements of power density be done.

That sends the message to the community that those limited surveys that Colonel Ashworth mentioned earlier were not sufficient to really tell people whether they were, indeed, below the standard or not.

So that's the message they have right now. It may be a risk communication message, but that's the message that's there.

The second message that's new that's there is Dr. Albanese is saying, "Well, wait a minute. It's not even power density. It's something else." We haven't been able to counter that.

There are discussions -- Colonel Ruscio didn't

mention, but there are panels that are supposedly in the planning stage to have Dr. Albanese and some other individuals debate, essentially, this issue. That probably, in itself, may not lead anywhere, but these are some of the things we're dealing with. These are the two main ones that I see.

DR. OSTROFF: Dennis?

DR. SHANAHAN: Dennis Shanahan. Let me ask a question. I mean, this issue of PAVE/PAWS not occurring in isolation, there's a lot more going on in terms of public relations in this community. The question I have is what has been done so far to clean up the superfund site?

I mean, clearly toxicological problems with water and all are much more related to cancer than this microwave by a bunch of studies. It may be that the community has lost confidence in the government for those reasons, that they haven't moved fast enough in taking care of problems that may be very real.

LT. COL. RUSCIO: Sir, I can answer part of that. Part of the answer, I think, is, yes, a loss of confidence has been there for many years due to multiple issues, I believe, related to DOD.

As far as the cleanup effort, the installation/restoration program has moved along, I think, exceedingly well. They have regained confidence within a large part of the community and DOD's commitment to clean up those

PLUMEs. We're successfully doing that.

The installation/restoration program is actually going into the maintenance phase, where the facilities will be treating for several years. It depends on what PLUME you're talking about.

The general consensus, I believe, is that DOD committed to the cleanup effort, followed through and did what it said it was going to do.

DR. KNORR: Just briefly --

DR. OSTROFF: Yeah, let's take two more comments and then we'll have to bring it to a close.

DR. KNORR: I just wanted to briefly add -- because that was an important question.

There has been a lot of attention given to those other types of contaminants. DOD did a study looking at the propellant bags, and response to that issue died away as a result of showing that there wasn't real exposure going on.

I really -- I think people are just frustrated that they've got this cancer problem and they don't know why. PAVE/PAWS is left as far as in the environment. So they're targeting that. There's always denial that it's some personal risk factor.

It's been our frustration that we couldn't get the Boston University researchers to make statements about the contribution of non-environmental risk factors to the cancer. It

just wasn't what they felt they designed the study to do. So they didn't want to make any statements about it. It's a lot of data waiting there to be looked at and shared with the community, but they didn't do it.

Silent Spring Institute is doing a big breast cancer study now. That result has environmental hypotheses, but hopefully we'll learn a little bit more about risk factors for breast cancer, which is a big concern there. We did a childhood cancer study on the Cape, which shows that there wasn't a problem. Mainly right now we're just hearing PAVE/PAWS.

DR. SHANAHAN: Well, it seems like you're doing all the right things.

DR. KNORR: Yeah.

AUDIENCE MEMBER: If I could thank you for the opportunity. Two very quick points. I'm a member of the Public Health Steering Committee that was formed to sort of guide through the whole process with PAVE/PAWS. I only have two points to make.

One speaks to what a community would do, what a community does when studying the impacts or trying to figure out what the impacts of this unknown beast on the hill is and when -- what -- just from -- a very credible source from Brooks Air Force Base -- says something and it's alarming. What does a community do?

Well, you're seeing what a community does.

Perhaps they overrespond.

How do we address it? You're right, it is a big public health -- it's a big public issue, how you get the community sort of turned around.

How do you address the fact that a very credible, in their eyes, source who works for the Air Force expresses concerns and uses words like "alarm" and uses words like "very concerned" and uses expressions like "no, I would not live down gradient of that thing on the hill".

How we turn that around is with good, credible information, part of which the process is occurring right here. If your board, if your panel says to the people of Cape Cod that, yes, you are the Air Force proceeding in a very logical manner using scientific method and are coming forth in a good process to determine whether this real impact is there. If you folks give the stamp to that and say you're doing it right, folks, then that is one step in the whole turning around the public attitude toward this.

From, you know, just a country bumpkin here sitting here when an Air Force person from Brooks says, "I'm alarmed. I'm concerned," without further looking into it, I can say, "Gee, you know, I'm starting to see the other side of this thing." Boy, in the beginning that was probably the thing that started it.

Yeah, we have other issues with the base. As

Lieutenant Colonel Ruscio said, he believes and I do too -- I live in the community -- that there is a very positive thing that the Air Force is doing in the cleanup. They've seen very quick responses. I sit on a couple of committees, issuing PLUME committees, some others.

We see genuine process, but there was no one on the other side of that saying, "Despite the progress you're making, I'm deeply concerned." Well, that's what did it. That "deeply concerned" was a big break. The community needs to know that a credible body of people, epidemiologists as one step, say, yes, you're proceeding correctly.

The other part is hearing from other credible investigators, pulling together their studies, the NRC, that will all turn the tide.

In answer to your question, do we have a public relations problem, yeah. It started with somebody saying, "I'm deeply concerned. I'm deeply alarmed," who had the credentials. Thank you.

DR. OSTROFF: Thank you. Thank you very much for those comments.

Let me ask Dr. Malmud -- and then we'll have to bring it to a close. I think Rick has one or two last comments.

DR. MALMUD: My first comment is a question, and that is, is there any scientist other than Dr. Albanese who adheres to Dr. Albanese's theory? I know that you don't, but --

MR. OSEPCHUK: No, no, no, I'm going to speak for many people. The people in my -- the reason you don't hear many people responding to it is because they don't believe it's worth their time.

Now, I try to point out that his ideas are flawed. Okay? A distinguished professor like Dr. Adair, Linda Adair's husband, Robert Adair, a member of the National Academy, spends his time and writes articles debunking Dr. Albanese's opinions; however, he maybe justifiably lost his temper and he used the homonym remark to characterize Dr. Albanese.

My point is that his theories -- let me put it this way. His theories are analogous to the discoveries of cold fusion. Now, when a discovery like that occurs, the person could either be a genius or something less. Maybe every 50 years a genius appears and his ideas are not accepted and eventually he wins. As Martin Garten pointed out, there's a continuous gradation between genius and quack. It's hard to distinguish sometimes where you are on the ladder. The fact of the matter is right now our committee has formally decided they're going to have to include Dr. Albanese's papers in our documented record of what's been looked at and what's been accepted and rejected.

Basically, many people don't have the motivation to look at his papers. By the way, his published paper in 1995 doesn't really go into some of these details that are now in the media. As I understand it, there's a letter to Colonel Ashworth

which, for the first time -- he didn't say this in his published papers -- that one volt per meter per nanosecond is the criteria for hazard. Never has that been published. Never has he shown a rationale. Why one? Why not two, three? Where did it come from?

My point is that his -- he's either a genius, of which I will have to apologize some day, or he's something less than a genius.

DR. OSTROFF: Thank you. Yeah?

DR. MALMUD: Am I to understand your answer to be that, to the best of your knowledge, there's no other recognized scientist who adheres to Dr. Albanese's theory?

MR. OSEPCHUK: That's correct.

DR. MALMUD: Thank you. So, really, in order to satisfy the community in which the facility is located, there are two issues. One is a scientific issue. That probably requires the publication or the dissemination of the information from the committee that was formed about a year ago.

The second issue is the epidemiologic issue, which is probably, from what we hear -- well, I'm only hearing it for the first time today -- probably more related to the superfund issue than to the facility. It seems we have to communicate with that community on two levels.

We live in a very interesting age. This is the age of science. It's also the age in which psychics consume more

television time than do scientists, much to the public's delight.

I think it's our responsibility to communicate more effectively than we have been on the issue. That's the only advice that I can give in this particular matter in that we have a community which obviously feels hurt by the government -- and the Air Force is a branch of the government. Therefore, they meet the government with understandable concern.

I think something has to be done to address the community's concern. I'm not certain, though, that it's an epidemiologic study, the repetition of an epidemiologic study.

DR. OSTROFF: Thanks. Bruce, if you don't mind, I'd just like Rick to make the last comments so that we can move on.

LT. COL. RIDDLE: I wanted to make one comment, and that was that Dr. Albanese was personally invited to attend this meeting and declined that invitation and asked me to do a literature search and provide that information to the board. He does have one publication with no data that I found in 1995, a couple of other older publications on some Agent Orange issues.

That one publication, I went a step further and I actually researched the number of times that that publication had been cited in other published literature. It had been cited 15 times. I think, in my recollection of the review of those abstracts, that they were in contradiction to the theories that

were put forward in that.

I do have his material. I will make it part of the public record for the board. I have that publication, and we have those 15 citations and papers that were published in response to that '95 publication.

DR. OSTROFF: Thank you very much. We're running a little late. Why don't we do this? Why don't we take a five-minute break and then the board will come back in executive session for the last 45 minutes?

(Executive session not recorded.)

(Meeting adjourned.)